

## 9. SAFETY RESULTS

### 9.1. DATA SET ANALYZED

All 281 (143 LUBRICOAT® Gel and 138 lactated Ringer's solution) patients who received treatment were included in the analysis of safety data.

### 9.2. DEMOGRAPHIC AND BASELINE FEATURES OF PATIENTS IN THE SAFETY POPULATION

The demographic and baseline features of patients in the safety data set (281 patients) are presented in the Supplemental Tables 2.1, 3.1, 4.1.1, and 4.2.1.

### 9.3. ADVERSE EVENTS

#### 9.3.1. Overall Adverse Events

Commonly reported adverse events (events reported by at least 5% of patients in any treatment group) are presented in Table 9.1. As shown, similar proportions of patients in the two treatment groups reported adverse events, except for allergic reaction for which significantly ( $p=0.048$ ) fewer patients in the LUBRICOAT® Gel group than in the lactated Ringer's solution reported the event. The two body systems with the highest patient incidence of adverse events were the body as a whole and the digestive system. Of events affecting the body as a whole, the largest proportions were attributable to pain. Digestive system disorders were frequently attributable to nausea, constipation, and flatulence. These events were expected given that patients were undergoing anesthesia and surgery.

Table 9.1: Incidence of Commonly ( $\geq 5\%$ ) Reported Adverse Events by Body System and  
 Preferred Term: Number (%) of Patients  
 Protocols PTL-0013 and PTL-0022

Body System Preferred Term	LUBRICOAT® Gel (N=143)	lactated Ringer's Solution (N=138)
<b>Body as a Whole</b>		
Pain	143 (100)	137 (99.3)
Headache	122 (85.3)	111 (80.4)
Abdominal pain	45 (31.5)	37 (26.8)
Fever	39 (27.3)	42 (30.4)
Back pain	25 (17.5)	19 (13.8)
Incision, inflammation	13 (9.1)	7 (5.1)
Incision pain	8 (5.6)	8 (5.8)
Allergic reaction	9 (6.3)	13 (9.4)
	3 (2.1)*	10 (7.2)
<b>Digestive</b>	100 (72.5)	
Nausea	66 (42.6)	65 (47.1)
Constipation	47 (32.9)	56 (40.6)
Flatulence	35 (24.5)	35 (25.4)
Vomiting	13 (9.1)	14 (10.1)
Dyspepsia	14 (9.8)	10 (7.2)
<b>Urogenital</b>	40 (29.0)	
Dysmenorrhea	44 (30.8)	22 (15.9)
	25 (17.5)	
<b>Nervous</b>	40 (29.0)	
Insomnia	37 (25.9)	22 (15.9)
Dizziness	20 (14.0)	13 (9.4)
	15 (10.5)	
<b>Respiratory</b>	26 (18.8)	
Cough, increased	30 (21.0)	8 (5.8)
Rhinitis	11 (7.7)	7 (5.1)
	8 (5.6)	
<b>Cardiovascular</b>	15 (10.9)	
Tachycardia	15 (10.5)	7 (5.1)
	4 (2.8)	
<b>Hemic and Lymphatic</b>	16 (11.6)	
Anemia	19 (13.3)	13 (9.4)
	12 (8.4)	
<b>Skin</b>	13 (9.4)	
Pruritus	13 (9.1)	10 (7.2)
	8 (5.6)	

\* Statistically significantly different from lactated Ringer's solution,  $p=0.048$ , Fisher's Exact test.

Cross Reference: Supplemental Tables 6.1. to 6.5.

### 9.3.3. Adverse Events by Relationship to Study Treatment

Adverse events considered by the investigator to be possibly, probably, or definitely related to study treatment was reported by 16 (11.2%) patients treated with LUBRICOAT® Gel and 7 (5.1%) patients treated with lactated Ringer's solution. These patients are listed in Table 9.2. All treatment-related events resolved spontaneously or with treatment and most resolved within 3 days.

Table 9.2: List of Patients with Treatment-Related Adverse Events  
Protocols PTL-0013 and PTL-0022

Treatment	Protocol No.	Patient No.	Age (yr)	Adverse Event (Literal Term)	Severity	Relationship	Start/Stop Dates	Outcome
LUBRICOAT® Gel	PTL-0013	[REDACTED]	33.0	incision pain, abdomen ileus	moderate severe	possibly possibly	12 Jan-30 Mar 98 16 Jan-19 Jan 98	resolved with treatment resolved with treatment
		[REDACTED]	36.2	bladder pain, infection	mild	possibly	19 Dec-25 Dec 96	resolved with treatment
		[REDACTED]	37.9	Klebsiella wound infection abdominal pain, suspect infection	moderate mild	possibly possibly	24 Jun-9 Jul 98 22 Jul-22 Jul 98	resolved with treatment resolved with treatment
		[REDACTED]	23.1	abdominal pain pain after surgery	severe moderate	possibly possibly	15 Nov-16 Nov 96 16 Nov-18 Nov 96	persisted resolved with treatment
		[REDACTED]	31.6	itching	moderate	possibly	07 Dec-08 Dec 96	resolved with treatment
		[REDACTED]	33.3	post-operative fever (to 101.4°F)	moderate	possibly	19 Feb-22 Feb 97	resolved with treatment
		[REDACTED]	38.8	potassium, decreased	moderate	possibly	21 Jan-27 Jan 97	resolved with treatment
		[REDACTED]	43.7	pruritus	mild	possibly	06 May-6 May 97	resolved with treatment
		[REDACTED]	4.9	elevated temperature* during hospitalization	mild	possibly	24 Dec-25 Dec 96	resolved with treatment
		[REDACTED]	39.3	post-operative pain	moderate	possibly	18 Sep-24 Sep 98	resolved with treatment

Table 9.2: (Continued) - List of Patients with Treatment-Related Adverse Events  
Protocols PTL-0013 and PTL-0022

Treatment	Protocol No.	Patient No.	Age (yr)	Adverse Event (Literal Term)	Severity	Relationship	Start/Stop Dates	Outcome
PTL-0022		[REDACTED]	37.7	post-operative pain	moderate	probably	10-Feb-	persisted
				post-operative fever*	moderate	possibly	11 Feb-15 Feb 98	resolved with treatment
				hypokalemia	moderate	possibly	13 Feb-16 Feb 98	resolved with treatment
				nausea	moderate	probably	14 Feb-	persisted
				abdominal distension	severe	definitely	14 Feb-16 Feb 98	resolved with treatment
				inflammation of incision	severe	definitely	14 Feb-19 Feb 98	resolved with treatment
				erythema of wound	mild	possibly	14 Feb-16 Feb 98	resolved spontaneously
				vulvar edema	mild	probably	14 Feb-16 Feb 98	resolved with treatment
				fluid collection in wound	severe	definitely	15 Feb-15 Feb 98	resolved with treatment
				gastric irritation	moderate	possibly	19 Feb-	persisted
				persisting pains	severe	possibly	04 Feb-14 Mar 97	resolved with treatment
				infection	severe	possibly	19 Nov-28 Nov 96	resolved with treatment
				rebound pain	mild	possibly	01-Aug-1 Aug 97	resolved spontaneously
				Nausea	moderate	possibly	16 Nov-17 Nov 96	resolved spontaneously
				nausea	moderate	possibly	04 Apr-05 Apr 97	resolved with treatment

Table 9.2: (Continued) - List of Patients With Treatment-Related Adverse Events  
Protocols PTL-0013 and PTL-0022

Treatment	Protocol No.	Patient No.	Age(yr)	Adverse Event (Literal Term)	Severity	Relationship	Start/Stop Dates	Outcome
<b>lactated Ringer's Solution</b>								
	PTL-0013	[REDACTED]	20.2	constipation	moderate	possibly	18 Mar-11 Apr 97	resolved with treatment
		[REDACTED]		vomiting	mild	possibly	04 Mar-18 Mar 97	resolved spontaneously
		[REDACTED]	28.4	constipation	moderate	possibly	03 Apr-03 Apr 97	resolved with treatment
		[REDACTED]	36.3	cramping, abdominal incision pain incision site bleeding incision surgical site pain incision pain	mild mild mild mild	possibly possibly possibly possibly	26 May-27 May 98 01 Jun-02 Jun 98 06 Jun-06 Jun 98 07 Jun-07 Jun 98 13 Jun-17 Jun 98	resolved spontaneously resolved with treatment resolved spontaneously resolved with treatment resolved with treatment
		[REDACTED]	36.2	low grade fever* fever of 101.5°F surgical site wound infection	mild mild moderate	possibly possibly possibly	06 Jul-07 Jul 98 13 Jul-13 Jul 98 13 Jul-23 Jul 98	resolved with treatment resolved with treatment resolved with treatment
		[REDACTED]	36.7	post-operative pain	severe	possibly	08 Jan-15 Jan 97	resolved with treatment
		[REDACTED]	29.4	elevated temperature*	severe	possibly	23 Jan-24 Jan 97	resolved with treatment
		[REDACTED]	34.0	elevated temperature (to 101 °F)	moderate	possibly	03 May-3 May 97	resolved with treatment

\* Temperature data not available.

Cross Reference: Data Listing 7.3.

#### 9.3.4. Adverse Events by Severity

Severe adverse events were reported by 33 (23.1%) patients treated with LUBRICOAT® Gel and 35 (25.4%) treated with the lactated Ringer's solution. All severe adverse events resolved spontaneously or with treatment and almost all resolved within 3 days. Seven patients (5 LUBRICOAT® Gel [2.5%] and 2 lactated Ringer's solution [1.4%]) reported severe adverse events considered by the investigator to be possibly related to the study treatment. These seven patients are included in the listing in Table 9.2. All patients with severe adverse events are listed in Data Listing 7.4.

#### 9.3.5. Serious Adverse Events

Serious adverse events occurred in 15 patients (8 LUBRICOAT® Gel and 7 lactated Ringer's solution).

Serious adverse events considered by the investigator to be related to study treatment were experienced by four patients (3 LUBRICOAT® Gel and 1 lactated Ringer's solution). Narratives for these four patients are provided in Appendix 13.

Serious adverse events considered by the investigator not to be associated with the device were experienced by eleven patients (5 LUBRICOAT® Gel and 6 lactated Ringer's Solution). Narratives of these eleven patients are provided in Appendix 13.

#### 9.3.6. Deaths or Discontinuations Due to an Adverse Event

There were no discontinuations due to an adverse event, and no deaths occurred during the study.

## 9.4. CLINICAL LABORATORY TESTS

### 9.4.1. Laboratory Mean Values

The mean values for laboratory parameters at baseline (prior to surgery) Visits 1 (within 3 days of the initial surgery), 2 (7 to 28 days after the initial surgery), and 3 (immediately prior to the second-look laparoscopy) are presented by treatment group in Supplemental Tables 7.1 to 7.4. There were no statistically significant differences between treatment groups at Visits 1, 2, or 3 for any of the clinical laboratory parameters, except for the following: WBC ( $8.89 \pm 3.19 \times 10^3/\text{mm}^3$  LUBRICOAT® Gel vs.  $7.87 \pm 2.50 \times 10^3/\text{mm}^3$  lactated Ringer's solution,  $p=0.004$ ), neutrophils ( $70.5 \pm 9.6\%$  vs.  $67.6 \pm 9.6\%$ ,  $p=0.016$ ), lymphocytes ( $19.7 \pm 7.6\%$  vs.  $21.9 \pm 8.1\%$ ,  $p=0.026$ ), and basophils ( $0.4 \pm 0.4\%$  vs.  $0.6 \pm 0.5\%$ ,  $p=0.026$ ) at Visit 1; and SGOT ( $18.2 \pm 7.92 \text{ IU/L}$  vs.  $20.8 \pm 10.0 \text{ IU/L}$ ,  $p=0.024$ ), and sodium ( $139.7 \pm 2.3 \text{ mEq/L}$  vs.  $140.3 \pm 2.2 \text{ mEq/L}$ ,  $p=0.023$ ) at Visit 2. The mean values of these laboratory tests were within the normal ranges of the respective hospitals and the relative differences were not considered clinically significant.

### 9.4.2. Shifts in Laboratory Values

Tables 9.3 to 9.5 summarize the number of patients whose pre-treatment laboratory value was normal but showed an out of normal range low or high value at Visit 1 (within 3 days of the initial surgery), Visit 2, (7 to 28 days after treatment), and at Visit 3 (immediately prior to the second-look laparoscopy). See also Supplemental Tables 8.1 to 8.23.

As expected in patients who had undergone recent surgery, normal to low or high shifts in several clinical laboratory parameters occurred in both treatment groups within 3 days of the initial surgery (Visit 1), reflecting factors such as surgical trauma and hemodilution.

At Visit 1, significantly higher proportion of patients in the LUBRICOAT® Gel group, than in the lactated Ringer's solution group had shifts from normal to high for WBCs ( 21.2% vs. 11.1%, p=0.027) and neutrophils (36.7% vs. 25.2%, p=0.005) and shifts from normal to low for lymphocytes (42.1% vs. 22.5%, p=0.001).

At Visit 2, fewer patients in both groups had shifts in laboratory parameters. The normal to high shift in WBC was no longer significant (p=0.245), but the proportion of patients in the LUBRICOAT® Gel group was higher than that in the lactated Ringer's solution group (10.5% vs. 3.9%). The normal to high shift in neutrophils and the normal to low shift in lymphocytes were still significant at Visit 2 (14.2% vs. 7.1%, p=0.026 for neutrophils and 15.8% vs. 8.8%, p=0.013 for lymphocytes). Also at Visit 2, significantly (p=0.034) fewer patients in the LUBRICOAT® Gel group than in the lactated Ringer's solution group had a shift in BUN, primarily due to a normal to low shift (0.8% vs. 7.0%).

At Visit 3, a significantly higher proportion of patients in the LUBRICOAT® Gel group than in the lactated Ringer's solution group had shifts in the following laboratory values: normal to low shift (3.2% vs. 0.8%) and normal to high shift (2.4% vs. 0%) for SGPT (p=0.015); and normal to low shift (4.1% vs. 2.5%) and normal to high shift (3.3% vs. 2.5%) for lymphocytes (p=0.032).

Shifts outside the normal ranges were considered not clinically significant. The elevations in neutrophils, first seen at Visit 1 and persisting through Visit 2 are discussed further in Section 9.4.3.

Table 9.3: Incidence of Blood Chemistry and Hematology Test Changes From  
 Pre-Treatment to Visit 1 (Within 3 Days of Initial Surgery)\*  
 Protocols PTL-0013 and PTL-0022

Laboratory Parameter	Shift	LUBRICOAT® Gel (N=143)		lactated Ringer's Solution (N=138)	
		N	%	N	%
BUN	Normal to Low	47 (134) <sup>b</sup>	35.1	44 (127)	34.6
	Normal to High	0 (134)	0.0	0 (127)	0.0
Creatinine	Normal to Low	10 (135)	7.4	12 (129)	9.3
	Normal to High	0 (135)	0.0	0 (129)	0.0
Phosphorus	Normal to Low	24 (119)	20.2	13 (118)	11.0
	Normal to High	3 (119)	2.5	2 (118)	1.7
Calcium	Normal to Low	51 (132)	38.6	42 (128)	32.8
	Normal to High	0 (132)	0.0	1 (128)	0.8
Uric Acid	Normal to Low	18 (122)	14.8	15 (118)	12.7
	Normal to High	0 (122)	0.0	0 (118)	0.0
Total Protein	Normal to Low	71 (128)	55.5	56 (124)	45.2
	Normal to High	0 (128)	0.0	0 (124)	0.0
Albumin	Normal to Low	74 (134)	55.2	65 (130)	50.0
	Normal to High	0 (134)	0.0	1 (130)	0.8
Total Bilirubin	Normal to Low	0 (130)	0.0	0 (124)	0.0
	Normal to High	2 (130)	1.5	2 (124)	1.6
SGOT	Normal to Low	0 (133)	0.0	2 (128)	1.6
	Normal to High	6 (133)	4.5	10 (128)	7.8
SGPT	Normal to Low	3 (124)	2.4	2 (119)	1.7
	Normal to High	3 (124)	2.4	6 (119)	5.0
Alkaline Phosphatase	Normal to Low	6 (131)	4.6	4 (127)	3.1
	Normal to High	0 (131)	0.0	1 (127)	0.8
Sodium	Normal to Low	2 (135)	1.5	2 (131)	1.5
	Normal to High	0 (135)	0.0	0 (131)	0.0
Potassium	Normal to Low	24 (135)	17.8	21 (131)	16.0
	Normal to High	0 (135)	0.0	0 (131)	0.0
Chloride	Normal to Low	2 (135)	1.5	0 (130)	0.0
	Normal to High	10 (135)	7.4	15 (130)	11.5
Hemoglobin	Normal to Low	60 (139)	43.2	71 (135)	52.6
	Normal to High	0 (139)	0.0	0 (135)	0.0

Table 9.3 (continued): Incidence of Blood Chemistry and Hematology Test Changes  
 From Pre-Treatment to Visit 1 (Day 3 After Treatment)\*  
 Protocols PTL-0013 and PTL-0022

Laboratory Parameter	Shift	LUBRICOAT® Gel (N=143)		lactated Ringer's Solution (N=138)	
		N	%	N	%
RBC	Normal to Low	58 (137)	42.3	62 (134)	46.3
	Normal to High	1 (137)	0.7	0 (134)	0.0
Hematocrit	Normal to Low	71 (139)	51.1	79 (135)	58.5
	Normal to High	0 (139)	0.0	0 (135)	0.0
WBC	Normal to Low	3 (137)	2.2	4 (135)	3.0
	Normal to High	29 (137)	21.2*	15 (135)	11.1
Neutrophils	Normal to Low	0 (120)	0.0	2 (119)	1.7
	Normal to High	44 (120)	36.7*	30 (119)	25.2
Lymphocytes	Normal to Low	51 (121)	42.1*	27 (120)	22.5
	Normal to High	0 (121)	0.0	1 (120)	0.8
Monocytes	Normal to Low	1 (121)	0.8	1 (121)	0.8
	Normal to High	7 (121)	5.8	3 (121)	2.5
Eosinophils	Normal to Low	2 (120)	1.7	4 (121)	3.3
	Normal to High	9 (120)	7.5	3 (121)	2.5
Basophils	Normal to Low	0 (119)	0.0	0 (120)	0.0
	Normal to High	2 (119)	1.7	2 (120)	1.7

\* Statistically significantly different from lactated Ringer's solution,  $p \leq 0.05$ , Fisher's Exact test.

Includes only patients whose pre-therapy laboratory value was normal but showed an out of range low or high value at Visit 1.

Values in parentheses represent the denominator

Cross Reference: Supplemental Tables 8.1 to 8.23

Table 9.4: Incidence of Blood Chemistry and Hematology Test Changes From  
 Pre-Treatment to Visit 2 (Day 7-28 After Treatment)\*  
 Protocols PTL-0013 and PTL-0022

Laboratory Parameter	Shift	LUBRICOAT® Gel (N=143)		lactated Ringer's Solution (N=138)	
		N	%	N	%
BUN	Normal to Low	1 (127)	0.8*	9 (129)	7.0
	Normal to High	0 (127)	0.0	1 (129)	0.8
Creatinine	Normal to Low	7 (129)	5.4	5 (128)	3.9
	Normal to High	1 (129)	0.8	1 (128)	0.8
Phosphorus	Normal to Low	2 (123)	1.6	2 (120)	1.7
	Normal to High	6 (123)	4.9	6 (120)	5.0
Calcium	Normal to Low	0 (126)	0.0	2 (121)	1.7
	Normal to High	1 (126)	0.8	3 (121)	2.5
Uric Acid	Normal to Low	5 (125)	4.0	2 (121)	1.7
	Normal to High	1 (125)	0.8	0 (121)	0.0
Total Protein	Normal to Low	0 (123)	0.0	3 (124)	2.4
	Normal to High	4 (123)	3.3	5 (124)	4.0
Albumin	Normal to Low	1 (128)	0.8	4 (126)	3.2
	Normal to High	1 (128)	0.8	2 (126)	1.6
Total Bilirubin	Normal to Low	0 (128)	0.0	1 (127)	0.8
	Normal to High	2 (128)	1.6	0 (127)	0.0
SGOT	Normal to Low	2 (129)	1.6	2 (128)	1.6
	Normal to High	2 (129)	1.6	5 (128)	3.9
SGPT	Normal to Low	2 (127)	1.6	4 (126)	3.2
	Normal to High	9 (127)	7.1	13 (126)	10.3
Alkaline Phosphatase	Normal to Low	1 (129)	0.8	1 (122)	0.8
	Normal to High	5 (129)	3.9	0 (122)	0.0
Sodium	Normal to Low	2 (130)	1.5	1 (129)	0.8
	Normal to High	0 (130)	0.0	0 (129)	0.0
Potassium	Normal to Low	0 (130)	0.0	0 (129)	0.0
	Normal to High	9 (130)	6.9	5 (129)	3.9
Chloride	Normal to Low	1 (129)	0.8	1 (128)	0.8
	Normal to High	1 (129)	0.8	7 (128)	5.5
Hemoglobin	Normal to Low	21 (124)	16.9	19 (128)	14.8
	Normal to High	1 (124)	0.8	0 (128)	0.0

Table 9.4 (continued): Incidence of Blood Chemistry and Hematology Test Changes  
 From Pre-Treatment to Visit 2 (Day 7-28 After Treatment)\*  
 Protocols PTL-0013 and PTL-0022

Laboratory Parameter	Shift	LUBRICOAT® Gel (N=143)		lactated Ringer's Solution (N=138)	
		N	%	N	%
RBC	Normal to Low	18 (124)	14.5	25 (127)	19.7
	Normal to High	2 (124)	1.6	1 (127)	0.8
Hematocrit	Normal to Low	23 (124)	18.5	28 (128)	21.9
	Normal to High	1 (124)	0.8	0 (128)	0.0
WBC	Normal to Low	2 (124)	1.6	1 (128)	0.8
	Normal to High	13 (124)	10.5	5 (128)	3.9
Neutrophils	Normal to Low	1 (113)	0.9	0 (113)	0.0
	Normal to High	16 (113)	14.2*	8 (113)	7.1
Lymphocytes	Normal to Low	18 (114)	15.8*	10 (114)	8.8
	Normal to High	1 (114)	0.9	2 (114)	1.8
Monocytes	Normal to Low	2 (114)	1.8	7 (114)	6.1
	Normal to High	3 (114)	2.6	1 (114)	0.9
Eosinophils	Normal to Low	3 (114)	2.6	1 (114)	0.9
	Normal to High	8 (114)	7.0	9 (114)	7.9
Basophils	Normal to Low	0 (113)	0.0	0 (114)	0.0
	Normal to High	4 (113)	3.5	8 (114)	7.0

\* Statistically significantly different from lactated Ringer's solution,  $p \leq 0.05$ , Fisher's Exact test.

Includes only patients whose pre-therapy laboratory value was normal but showed an out of range low or high value at Visit 2.

\* Values in parentheses represent the denominator

Cross Reference: Supplemental Tables 8.1 to 8.23

Table 9.5: Incidence of Blood Chemistry and Hematology Test Changes From Pre-Treatment to Visit 3 (Immediately Prior to Second-Look Laparoscopy)\*  
 Protocols PTL-0013 and PTL-0022

Laboratory Parameter	Shift	LUBRICOAT® Gel (N=143)		lactated Ringer's Solution (N=138)	
		N	%	N	%
BUN	Normal to Low	7 (128)	5.5	3 (130)	2.3
	Normal to High	0 (128)	0.0	0 (130)	0.0
Creatinine	Normal to Low	2 (130)	1.5	7 (129)	5.4
	Normal to High	0 (130)	0.0	0 (129)	0.0
Phosphorus	Normal to Low	1 (124)	0.8	1 (122)	0.8
	Normal to High	2 (124)	1.6	4 (122)	3.3
Calcium	Normal to Low	0 (128)	0.0	2 (126)	1.6
	Normal to High	0 (128)	0.0	1 (126)	0.8
Uric Acid	Normal to Low	6 (126)	4.8	3 (122)	2.5
	Normal to High	0 (126)	0.0	1 (122)	0.8
Total Protein	Normal to Low	4 (123)	3.3	5 (126)	4.0
	Normal to High	3 (123)	2.4	3 (126)	2.4
Albumin	Normal to Low	1 (129)	0.8	5 (129)	3.0
	Normal to High	2 (129)	1.6	3 (129)	2.3
Total Bilirubin	Normal to Low	0 (129)	0.0	1 (128)	0.8
	Normal to High	1 (129)	0.8	0 (128)	0.0
SGOT	Normal to Low	2 (129)	1.6	1 (128)	0.8
	Normal to High	2 (129)	1.6	3 (128)	2.3
SGPT	Normal to Low	4 (126)	3.2*	1 (123)	0.8
	Normal to High	3 (126)	2.4*	0 (123)	0.0
Alkaline Phosphatase	Normal to Low	2 (129)	1.6	2 (126)	1.6
	Normal to High	1 (129)	0.8	1 (126)	0.8
Sodium	Normal to Low	1 (130)	0.8	0 (130)	0.0
	Normal to High	1 (130)	0.8	0 (130)	0.0
Potassium	Normal to Low	1 (129)	0.8	3 (129)	2.3
	Normal to High	0 (129)	0.0	0 (129)	0.0
Chloride	Normal to Low	0 (126)	0.0	1 (126)	0.8
	Normal to High	8 (126)	6.3	9 (126)	7.1
Hemoglobin	Normal to Low	5 (132)	3.8	11 (132)	8.3
	Normal to High	0 (132)	0.0	0 (132)	0.0

Table 9.5 (continued): Incidence of Blood Chemistry and Hematology Test Changes  
 From Pre-Treatment to Visit 3 (Immediately Prior to Second-Look Laparoscopy)<sup>a</sup>  
 Protocols PTL-0013 and PTL-0022

Laboratory Parameter	Shift	LUBRICOAT® Gel (N=143)		lactated Ringer's Solution (N=138)	
		N	%	N	%
RBC	Normal to Low	8 (132)	6.1	11 (132)	8.3
	Normal to High	1 (132)	0.8	0 (132)	0.0
Hematocrit	Normal to Low	8 (132)	6.1	10 (133)	7.5
	Normal to High	0 (132)	0.0	0 (133)	0.0
WBC	Normal to Low	3 (132)	2.3	12 (132)	9.1
	Normal to High	5 (132)	3.8	6 (132)	4.5
Neutrophils	Normal to Low	2 (123)	1.6	2 (119)	1.7
	Normal to High	6 (123)	4.9	2 (119)	1.7
Lymphocytes	Normal to Low	5 (123)	4.1*	3 (120)	2.5
	Normal to High	4 (123)	3.3*	3 (120)	2.5
Monocytes	Normal to Low	1 (122)	0.8	3 (120)	2.5
	Normal to High	5 (122)	4.1	5 (120)	4.2
Eosinophils	Normal to Low	4 (122)	3.3	4 (120)	3.3
	Normal to High	2 (122)	1.6	5 (120)	4.2
Basophils	Normal to Low	0 (121)	0.0	0 (119)	0.0
	Normal to High	6 (121)	5.0	3 (119)	2.5

\* Statistically significantly different from lactated Ringer's solution, p<0.05, Fisher's Exact test.

<sup>a</sup> Includes only patients whose pre-therapy laboratory value was normal but showed an out of range low or high value at Visit 3.

<sup>b</sup> Values in parentheses represent the denominator

Cross Reference: Supplemental Tables 8.1 to 8.23

#### 9.4.3. Elevations in WBC and Neutrophil Count

A slight increase in mean WBC concentration was seen at Visit 1 in the patients who received LUBRICOAT® Gel compared to the patients who received lactated Ringer's solution ( $8.89 \times 10^3/\text{mm}^3$  vs.  $7.87 \times 10^3/\text{mm}^3$ ; p=0.004) (Supplemental Tables 7.1 to 7.4). This increase was primarily due to an increase in the number of neutrophils (70.5%, 67.6%; p=0.016) in 36.7% and 25.2% of the patients with normal values at baseline, respectively. This difference in mean WBC

concentration was not seen at the other visits. A trend was noted in the number of patients who shifted from the group with normal WBC concentration at baseline to high concentration at Visits 1, 2 and 3 in LUBRICOAT® Gel-treated patients compared to controls ( $p=0.027$ , 0.245, and 0.313, respectively). A statistically significant number of patients shifted from the groups with normal percentage of neutrophils at baseline to a high percentage at Visits 1 and 2 compared to control patients ( $p=0.005$  and 0.026). Although the difference between the groups in the proportion of patients with shifts in neutrophils was not significant at Visit 3, it approached statistical significance ( $p=0.090$ ). Subgroup analysis was performed to assess correlation between elevated WBC concentrations and center, continent, fever, adhesion formation (Modified AFS score), duration of hospitalization, surgical time and blood loss. No correlation was found.

Three of the eight patients in the study with infection listed as an adverse event had normal WBC which became elevated at Day 3. In the LUBRICOAT® Gel group, 2 of the 29 patients with elevated WBC were listed as having an infection. In one case (patient [REDACTED] this was a fungal infection of the vagina which was treated on postoperative day 2 and resolved the following day. The other patient (patient [REDACTED] was suspected of having an infection on postoperative day 7, which was ruled out by laparoscopic evaluation of the pelvis, negative peritoneal fluid and urine cultures, and an afebrile course. She was diagnosed as having irritable bowel syndrome. At a follow up visit, 10 days later, she was treated with Bactrim for a urinary tract infection. In the lactated Ringer's solution group, 1 of the 15 patients with elevated WBC was listed as having an infection. This patient (1101) had an incisional wound infection.

No pattern of clinical sequelae (including infection and intraperitoneal adhesions) with patients with elevated WBC and/or neutrophils shifts was identified which was considered to be clinically significant. Since these findings of a low, transient

elevation of WBC concentration was not common to any particular center, demographic, or clinical manifestation, it was considered to be a brief, subclinical response without clinical significance.

#### 9.4.4. Abdominal Auscultation and Percussion

Abdominal auscultation and percussion data are summarized in Supplemental Table 9. There were no significant differences between the treatment groups for bowel sounds, fluid wave, or rebound pain within 3 days after, and 7 to 28 days after the initial surgery.

#### 9.4.5. Gross Evaluation at Second-Look Laparoscopy

At second-look laparoscopy, no unusual lesions were noted for patients in either treatment group (refer to Data Listing 10.5). Brownish discolorations on some peritoneal surfaces were noted for 15 patients in the LUBRICOAT® Gel group [REDACTED] [REDACTED] [REDACTED], [REDACTED] [REDACTED] [REDACTED] and 4 in the control group ([REDACTED]).

### 10. SUMMARY AND DISCUSSION

This randomized, third-party blinded, parallel group, placebo-controlled, multi-center clinical study evaluated the safety and efficacy for female patients aged 18.6 to 45.9 years undergoing peritoneal cavity surgery by laparotomy who received a single intraperitoneal instillation of 300 mL LUBRICOAT® Gel or lactated Ringer's solution to prevent or reduce post-surgical adhesion formation. Efficacy was evaluated approximately 6 to 12 weeks after the initial surgery during a second-look laparoscopic procedure. Two hundred eighty-one patients were evaluable for safety and 265 were evaluable for efficacy.

The primary efficacy variable was the Modified AFS score based on 24 anatomical sites in the pelvis and abdomen. Secondary efficacy variables were the proportion of sites with adhesions and the extent and severity of adhesions. Adhesions were characterized as *de novo* versus reformed, surgical versus non-surgical, and pelvic versus abdominal. Adhesions at all surgical sites, pelvic sites only, general surgical sites only, and at each individual anatomical site were evaluated. Safety was assessed based on adverse events recorded throughout the study, on clinical laboratory tests performed at baseline and post-therapy, and on gross evaluation at second-look.

Treatment with LUBRICOAT® Gel in patients undergoing peritoneal cavity surgery was found to be superior to treatment with lactated Ringer's solution in reducing post-surgical adhesions. When all adhesion sites were considered, the LUBRICOAT® Gel was found to be significantly more effective than lactated Ringer's solution in reducing post-surgical adhesions (based on the Modified AFS score from 24 anatomical sites). Patients treated with LUBRICOAT® Gel had an overall average score that was 45% lower than that of patients treated with lactated Ringer's solution. The proportion of sites with new adhesions, and the severity and extent of post-surgical adhesions were also significantly reduced in patients treated with LUBRICOAT® Gel. The gel was also found to be significantly more effective than the control solution in reducing *de novo* and reformed adhesions, and adhesions at surgical and non-surgical sites.

When the abdominal sites or pelvic sites were considered separately, LUBRICOAT® Gel was found to be significantly more effective than the control solution in reducing the incidence, extent and severity of adhesions, *de novo* and reformed adhesions, and surgical and non-surgical adhesions. Similarly, a reduction in adhesions with LUBRICOAT® Gel was observed in patients with endometriosis as well as those without endometriosis, whether sutures were used, and regardless of the method of adhesiolysis, i.e. sharp dissection, blunt

dissection, or cautery (lasers were used too infrequently to comment). A reduction in adhesions with LUBRICOAT® Gel was also found for all subgroups of patients based on the surgical procedure performed: patients with myomectomy, patients without myomectomy, patients with adhesiolysis, patients with tubal procedures, patients with ovarian procedures, patients with dermoid ovarian procedures, patients with endometrioma ovarian procedures, and patients with endometriosis excision.

The effect of LUBRICOAT® Gel on reducing adnexal adhesions was shown by a significant reduction in the Standard AFS score compared to lactated Ringer's solution. The minimum score of both the right and left adnexa was reduced by 59% following administration of LUBRICOAT® Gel. In addition, the proportion of patients with minimal scores (Standard AFS score 0-5) increased in the patient group that received LUBRICOAT® Gel and decreased in the lactated Ringer's solution group. Similarly, the proportion of patients with mild, moderate or severe Standard AFS scores (6-10, 11-20, 21-32, respectively) decreased in the group that received LUBRICOAT® Gel and increased in the group that received lactated Ringer's solution.

Regardless of population, covariate analyses indicated LUBRICOAT® Gel produced significantly lower Modified AFS scores than Lactated Ringer's solution. The effect of center was always at least marginally significant when US and European centers were both in the analysis but was absent when the US and European centers were analyzed alone. However, the treatment x center interaction never approached statistical significance indicating that, although some centers may have had higher overall adhesion scores than others, treatment with LUBRICOAT® Gel reduced adhesion scores and therefore the data are combinable.

The safety profile of patients treated with LUBRICOAT® Gel was comparable to those treated with lactated Ringer's solution. All patients in both treatment groups reported having at least one adverse event. The most frequently reported patient complaints in both treatment groups were pain (85.3% vs. 80.4%), nausea (42.6% vs. 47.1%), constipation (32.9% vs. 40.6%), headache (31.5% vs. 26.8%), abdominal pain (27.3 vs. 30.4%), and flatulence (24.5% vs. 25.4%). These expected events (given that patients were undergoing anesthesia and surgery) were generally mild to moderate and all resolved spontaneously or with treatment. Sixteen (11.2%) patients treated with LUBRICOAT® Gel and five patients (4.7%) treated with lactated Ringer's solution experienced adverse events considered by the investigator to be possibly, probably, or definitely related to treatment. These events included abdominal and/or post-operative pain, fever, nausea, and constipation, and all resolved spontaneously or with treatment. Treatment-related serious adverse events were experienced by four patients in the LUBRICOAT® Gel group (two cases of abdominal pain, one case of fever, and one case of post-operative ileus) and one patient in the lactated Ringer's solution group (fever). These patients were treated with medications or additional surgical procedure. There were no discontinuations due to an adverse event and no deaths occurred during the study.

As expected in patients who had undergone recent surgery, normal to low or high shifts in several clinical laboratory parameters occurred in both treatment groups within 3 days of the initial surgery (Visit 1), reflecting factors such as surgical trauma and hemodilution. By Visit 3 (immediately prior to the second-look laparoscopy), most parameters were within the normal ranges in both treatment groups. Shifts outside the normal ranges were considered not clinically significant. Elevations in WBCs, primarily due to an increase in the number of neutrophils, first seen at Visit 1, persisted through Visit 2, and returned to normal by Visit 3. Subgroup analysis indicated that there was no correlation between elevated WBC concentrations and center, continent, fever, adhesion formation

(Modified AFS score), duration of hospitalization, surgical time, and blood loss. No clinical sequelae (including infection and intraperitoneal adhesions) with patients with elevated WBC and/or neutrophils shifts was identified which was considered to be clinically significant. Since these findings of a low, transient elevation of WBC concentration was not common to any particular center, demographic, or clinical manifestation, it was considered to be a brief, subclinical response without clinical significance.

## 11. CONCLUSIONS

A single intraperitoneal instillation of 300 mL LUBRICOAT® Gel in female patients undergoing peritoneal cavity surgery by laparotomy was safe and effective in improving adhesion outcome:

- The mean Modified AFS score for 24 sites throughout the peritoneal cavity was significantly ( $p<0.05$ ) lower in the LUBRICOAT® Gel group than in the lactated Ringer's solution group.
- The minimum Standard AFS score of both the right and left adnexa was significantly ( $p<0.05$ ) lower in the LUBRICOAT® Gel group than in the lactated Ringer's solution group.
- The proportion of sites with post-surgical adhesions were significantly ( $p<0.05$ ) fewer in the LUBRICOAT® Gel group than in the lactated Ringer's solution group.
- The severity and extent of post-surgical adhesions were significantly ( $p<0.05$ ) less in the LUBRICOAT® Gel group than in the lactated Ringer's solution group.
- *De novo* and reformed adhesions were significantly ( $p<0.05$ ) reduced in the LUBRICOAT® Gel group than in the lactated Ringer's solution group.

- The reduction in adhesions was observed whether all 24 sites were considered, only the general surgical sites were considered, or only the pelvic sites were considered.
- The reduction in adhesions was observed regardless of the presence or absence of endometriosis, the use of sutures, the method of adhesiolysis, or the surgical procedure, including myomectomy, adhesiolysis, tubal and ovarian surgery.
- The safety profile (i.e., adverse event incidence rates, clinical laboratory test results) of patients treated with LUBRICOAT® Gel was comparable to those treated with lactated Ringer's solution.

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Lubricoat Gel versus Lactated Ringer's solution for Prevention of Adhesions  
Protocol PTL-0013 and PTL-0022

TABLE 1: Patients Randomized

Center	Lubricoat Gel				Lactated Ringer's Solution			
	Completed	No 2nd Look	Untreated	Unused	Completed	No 2nd Look	Untreated	Unused
2	21	3	3	1	18	2	6	1
3	6	.	.	.	5	.	1	.
4	4	.	.	.	3	.	.	.
5	.	1	.	.	.	.	.	.
6	6	.	4	.	8	.	1	2
7	5	.	.	.	6	.	.	.
8	6	.	1	.	7	.	.	.
9	12	.	.	.	10	.	1	1
10	14	.	.	.	13	.	.	1
11	15	4	1	.	17	.	2	.
12	4	1	2	1	8	1	1	.
21	12	2	.	4	14	1	.	2
23	10	1	.	3	9	.	.	5
25	5	.	2	.	8	.	.	.
27	5	.	.	.	3	.	.	1
29	6	.	.	.	5	.	1	.
ALL	131	12	9	13	134	4	13	13

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**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 2.1: Demographics, Height, Weight and Vital Signs - ITT Population

Variable	Lubricote Gel			Lactated Ringer's Solution			P		
	n	N	%	n	N	%			
Race									
Caucasian	78	/ 143	54.5%	83	/ 138	60.1%	0.399		
Black	31	/ 143	21.7%	24	/ 138	17.4%	0.372		
Oriental	5	/ 143	3.5%	4	/ 138	2.9%	1.000		
Hispanic	24	/ 143	16.8%	24	/ 138	17.4%	1.000		
Other	5	/ 143	3.5%	3	/ 138	2.2%	0.723		
Variable	N	Mean	(SD)	Range	N	Mean	(SD)	Range	P
Age (years)	143	33.8	(5.7)	18.8 to 44.9	138	34.0	(5.5)	18.6 to 45.9	0.691
Temperature (F)	135	98.1	(0.8)	95.9 to 99.9	135	98.3	(0.6)	96.0 to 99.7	0.067
Pulse (bpm)	139	74.9	(10.9)	45 to 110	136	74.6	(10.9)	50 to 109	0.818
Respiration (min)	123	18.3	(3.7)	10 to 32	116	19.2	(6.1)	10 to 64	0.177
Systolic BP (mmHg)	143	119.7	(14.3)	92 to 162	137	120.2	(13.9)	80 to 168	0.783
Diastolic BP (mmHg)	143	73.7	(10.8)	47 to 108	137	73.5	(10.8)	42 to 104	0.898
Height (in)	141	64.4	(2.6)	57.0 to 72.4	138	64.5	(3.0)	56.0 to 71.7	0.790
Weight (lbs)	143	150.0	(30.6)	103 to 252	138	150.1	(31.6)	100 to 264	0.980

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 p values determined using the Fisher exact test or Student's t test

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 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 2.2: Demographics, Height, Weight and Vital Signs - Patients Completing the Study

Variable	Lubricote Gel			Lactated Ringer's Solution			P		
	n	N	%	n	N	%			
Race									
Caucasian	74	/ 131	56.5%	82	/ 134	61.2%	0.456		
Black	28	/ 131	21.4%	23	/ 134	17.2%	0.437		
Oriental	4	/ 131	3.1%	4	/ 134	3.0%	1.000		
Hispanic	20	/ 131	15.3%	22	/ 134	16.4%	0.867		
Other	5	/ 131	3.8%	3	/ 134	2.2%	0.497		
Variable	N	Mean	(SD)	Range	N	Mean	(SD)	Range	P
Age (years)	131	33.8	(5.8)	18.8 to 44.9	134	34.2	(5.4)	18.6 to 45.9	0.637
Temperature (F)	125	98.1	(0.8)	95.9 to 99.9	131	98.3	(0.6)	96.0 to 99.7	0.079
Pulse (bpm)	128	75.1	(11.2)	45 to 110	132	74.8	(10.9)	50 to 109	0.811
Respiration (min)	114	18.3	(3.7)	10 to 32	113	19.2	(6.1)	10 to 64	0.174
Systolic BP (mmHg)	131	120.1	(14.5)	92 to 162	133	119.9	(13.9)	80 to 168	0.900
Diastolic BP (mmHg)	131	73.7	(11.1)	47 to 108	133	73.7	(10.6)	42 to 104	0.998
Height (in)	130	64.5	(2.5)	57.0 to 71.0	134	64.6	(2.9)	57.0 to 71.7	0.690
Weight (lbs)	131	150.1	(30.9)	104 to 252	134	150.2	(31.8)	100 to 264	0.994

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LIFECORE, INC.  
Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
Protocol PTL-0013 and PTL-0022

TABLE 2.3: Demographics, Height, Weight and Vital Signs - Patients with no Second Look

Variable	Lubricote Gel			Lactated Ringer's Solution			P		
	n	N	%	n	N	%			
Race									
Caucasian	4	12	33.3%	1	4	25.0%	1.000		
Black	3	12	25.0%	1	4	25.0%	1.000		
Oriental	1	12	8.3%	0	4	0.0%	1.000		
Hispanic	4	12	33.3%	2	4	50.0%	0.604		
Other	0	12	0.0%	0	4	0.0%	0.604		
Variable	N	Mean	(SD)	Range	N	Mean	(SD)	Range	P
Age (years)	12	33.0	(4.7)	24.9 to 40.2	4	29.8	(6.2)	23.2 to 37.9	0.293
Temperature (F)	10	98.3	(0.6)	97.0 to 99.2	4	98.7	(0.8)	97.8 to 99.4	0.316
Pulse (bpm)	11	73.2	(6.6)	62 to 82	4	70.5	(11.4)	61 to 84	0.575
Respiration (min)	9	19.1	(4.5)	14 to 30	3	20.0	(0.0)	20 to 20	0.746
Systolic BP (mmHg)	12	116.2	(11.7)	94 to 133	4	132.0	(7.4)	127 to 143	0.025
Diastolic BP (mmHg)	12	74.0	(8.1)	62 to 85	4	69.0	(18.1)	58 to 96	0.446
Height (in)	11	63.9	(3.8)	59.0 to 72.4	4	61.5	(4.5)	56.0 to 66.9	0.317
Weight (lbs)	12	148.2	(28.3)	103 to 201	4	146.8	(22.9)	121 to 177	0.930

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 3.1: Previous and Concomitant Medications - ITT Population

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
Antihistamine Drugs	31	143	21.7%	31	138	22.5%	0.887
Anti-infective Agents	110	143	76.9%	111	138	80.4%	0.561
Antineoplastic Agents	1	143	0.7%	2	138	1.4%	0.617
Autonomic Drugs	115	143	80.4%	110	138	79.7%	0.883
Blood Derivatives	1	143	0.7%	2	138	1.4%	0.617
Blood Formation / Anticoag	48	143	33.6%	38	138	27.5%	0.301
Cardiovascular Drugs	8	143	5.6%	8	138	5.8%	1.000
CNS Agents	143	143	100.0%	138	138	100.0%	1.000
Diagnostic Agents	0	143	0.0%	1	138	0.7%	0.491
Electrolytic / Caloric Agents	13	143	9.1%	22	138	15.9%	0.104
Expectorants/Cough Preparations	15	143	10.5%	8	138	5.8%	0.193
EENT Preparations	5	143	3.5%	7	138	5.1%	0.567
Gastrointestinal Drugs	121	143	84.6%	119	138	86.2%	0.738
Heavy Metal Antagonists	0	143	0.0%	1	138	0.7%	0.491
Hormones	68	143	47.6%	66	138	47.8%	1.000
Local Anesthetics	62	143	43.4%	57	138	41.3%	0.809
Oxytocics	0	143	0.0%	1	138	0.7%	0.491
Vaccines	1	143	0.7%	0	138	0.0%	1.000
Skin / Mucous Membrane Agents	15	143	10.5%	12	138	8.7%	0.688
Smooth Muscle Relaxants	3	143	2.1%	0	138	0.0%	0.248
Vitamins	50	143	35.0%	38	138	27.5%	0.199
Mineral Supplements	9	143	6.3%	7	138	5.1%	0.798
Herbal/Nutritional Preparations	24	143	16.8%	13	138	9.4%	0.079
Unclass. Therapeutic Agents	5	143	3.5%	2	138	1.4%	0.448
Devices	0	143	0.0%	1	138	0.7%	0.491

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LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 3.2: Previous and Concomitant Medications - Patients Completing the Study

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
Antihistamine Drugs	30	131	22.9%	31	134	23.1%	1.000
Anti-infective Agents	101	131	77.1%	108	134	80.6%	0.548
Antineoplastic Agents	1	131	0.8%	2	134	1.5%	1.000
Autonomic Drugs	107	131	81.7%	106	134	79.1%	0.644
Blood Derivatives	1	131	0.8%	2	134	1.5%	1.000
Blood Formation / Anticoag	44	131	33.6%	37	134	27.6%	0.351
Cardiovascular Drugs	8	131	6.1%	8	134	6.0%	1.000
CNS Agents	131	131	100.0%	134	134	100.0%	1.000
Diagnostic Agents	0	131	0.0%	1	134	0.7%	1.000
Electrolytic / Caloric Agents	12	131	9.2%	21	134	15.7%	0.137
Expectorants/Cough Preparations	15	131	11.5%	8	134	6.0%	0.130
EENT Preparations	5	131	3.8%	7	134	5.2%	0.769
Gastrointestinal Drugs	112	131	85.5%	116	134	86.6%	0.860
Heavy Metal Antagonists	0	131	0.0%	1	134	0.7%	1.000
Hormones	62	131	47.3%	64	134	47.8%	1.000
Local Anesthetics	59	131	45.0%	56	134	41.8%	0.621
Oxytocics	0	131	0.0%	0	134	0.0%	1.000
Vaccines	1	131	0.8%	0	134	0.0%	0.494
Skin / Mucous Membrane Agents	14	131	10.7%	12	134	9.0%	0.683
Smooth Muscle Relaxants	3	131	2.3%	0	134	0.0%	0.119
Vitamins	49	131	37.4%	38	134	28.4%	0.150
Mineral Supplements	9	131	6.9%	7	134	5.2%	0.615
Herbal/Nutritional Preparations	24	131	18.3%	13	134	9.7%	0.051
Unclass. Therapeutic Agents	5	131	3.8%	2	134	1.5%	0.278
Devices	0	131	0.0%	1	134	0.7%	1.000

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p values determined using Fisher exact tests

**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

**TABLE 3.3: Previous and Concomitant Medications - Patients with no Second Look**

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
Antihistamine Drugs	1	12	8.3%	0	4	0.0%	1.000
Anti-infective Agents	9	12	75.0%	3	4	75.0%	1.000
Antineoplastic Agents	0	12	0.0%	0	4	0.0%	1.000
Autonomic Drugs	8	12	66.7%	4	4	100.0%	0.516
Blood Derivatives	0	12	0.0%	0	4	0.0%	1.000
Blood Formation / Anticoag	4	12	33.3%	1	4	25.0%	1.000
Cardiovascular Drugs	0	12	0.0%	0	4	0.0%	1.000
CNS Agents	12	12	100.0%	4	4	100.0%	1.000
Diagnostic Agents	0	12	0.0%	0	4	0.0%	1.000
Electrolytic / Caloric Agents	1	12	8.3%	1	4	25.0%	0.450
Expectorants/Cough Preparations	0	12	0.0%	0	4	0.0%	1.000
EENT Preparations	0	12	0.0%	3	4	75.0%	1.000
Gastrointestinal Drugs	9	12	75.0%	0	4	0.0%	1.000
Heavy Metal Antagonists	0	12	0.0%	2	4	50.0%	1.000
Hormones	6	12	50.0%	1	4	25.0%	1.000
Local Anesthetics	3	12	25.0%	1	4	25.0%	0.250
Oxytocics	0	12	0.0%	0	4	0.0%	1.000
Vaccines	0	12	0.0%	0	4	0.0%	1.000
Skin / Mucous Membrane Agents	1	12	8.3%	0	4	0.0%	1.000
Smooth Muscle Relaxants	0	12	0.0%	0	4	0.0%	1.000
Vitamins	1	12	8.3%	0	4	0.0%	1.000
Mineral Supplements	0	12	0.0%	0	4	0.0%	1.000
Herbal/Nutritional Preparations	0	12	0.0%	0	4	0.0%	1.000
Unclass. Therapeutic Agents	0	12	0.0%	0	4	0.0%	1.000
Devices	0	12	0.0%	0	4	0.0%	

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LIFECORE, INC.  
 Lubricoat Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 4.1.1: Operative Characteristics - ITT Population

Variable	Lubricoat Gel			Lactated Ringer's Solution			P		
	n	N	%	n	N	%			
Adhesions	75	143	52.4%	73	138	52.9%	1.000		
Endometriosis	26	143	18.2%	29	138	21.0%	0.652		
Stage I	10	26	38.5%	9	29	31.0%	0.584		
Stage II	4	26	15.4%	11	29	37.9%	0.076		
Stage III	6	26	23.1%	5	29	17.2%	0.739		
Stage IV	6	26	23.1%	4	29	13.8%	0.490		
Transfusions	8	143	5.6%	4	138	2.9%	0.378		
Variable	N	Mean	(SD)	Range	N	Mean	(SD)	Range	P
Blood Loss (mL)	143	213	(213)	0 to 1500	138	223	(281)	2 to 2200	0.737
Blood Units	143	0.14	(0.63)	0.00 to 4.00	138	0.08	(0.48)	0.00 to 4.00	0.374
Operative Time (hrs)	143	1.88	(0.84)	0.75 to 5.00	138	1.80	(0.84)	0.75 to 5.00	0.447
Days to Discharge	143	2.9	(1.6)	0 to 12	138	3.0	(1.6)	0 to 10	0.724

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

**TABLE 4.1.2: Operative Characteristics - Patients Completing the Study**

Variable	Lubricote Gel			Lactated Ringer's Solution			P		
	n	N	%	n	N	%			
Adhesions	70	131	53.4%	71	134	53.0%	1.000		
Endometriosis	23	131	17.6%	29	134	21.6%	0.441		
Stage I	9	23	39.1%	9	29	31.0%	0.571		
Stage II	4	23	17.4%	11	29	37.9%	0.132		
Stage III	4	23	17.4%	5	29	17.2%	1.000		
Stage IV	6	23	26.1%	4	29	13.8%	0.307		
Transfusions	8	131	6.1%	4	134	3.0%	0.251		
Variable	N	Mean	(SD)	Range	N	Mean	(SD)	Range	P
Blood Loss (mL)	131	214	(214)	2 to 1500	134	224	(284)	2 to 2200	0.742
Blood Units	131	0.15	(0.66)	0.00 to 4.00	134	0.08	(0.49)	0.00 to 4.00	0.324
Operative Time (hrs.)	131	1.86	(0.82)	0.75 to 5.00	134	1.80	(0.85)	0.75 to 5.00	0.533
Days to Discharge	131	3.0	(1.6)	0 to 12	134	3.0	(1.7)	0 to 10	0.909
Days to 2nd Look	131	60.4	(26.2)	26 to 245	134	58.7	(21.4)	31 to 145	0.561

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LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
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TABLE 4.1.3: Operative Characteristics - Patients with no Second Look

Variable	Lubricote Gel			Lactated Ringer's Solution			P		
	n	N	%	n	N	%			
Adhesions	5	12	41.7%	2	4	50.0%	1.000		
Endometriosis	3	12	25.0%	0	4	0.0%	0.529		
Stage I	1	3	33.3%	.	0	.	.		
Stage II	0	3	0.0%	.	0	.	.		
Stage III	2	3	66.7%	.	0	.	.		
Stage IV	0	3	0.0%	.	0	.	.		
Transfusions	0	12	0.0%	0	4	0.0%	.		
Variable	N	Mean	(SD)	Range	N	Mean	(SD)	Range	P
Blood Loss (mL)	12	204	(212)	0 to 700	4	188	(144)	100 to 400	0.890
Blood Units	12	0.00	(0.00)	0.00 to 0.00	4	0.00	(0.00)	0.00 to 0.00	.
Operative Time (hrs)	12	2.04	(1.06)	0.90 to 4.00	4	1.88	(0.63)	1.00 to 2.50	0.779
Days to Discharge	12	2.3	(1.4)	0 to 5	4	2.5	(0.6)	2 to 3	0.730

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LIFECORE, INC.  
 Lubricant Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 4.2.1: Surgical Procedures - ITT Population

Variable	Lubricant Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
APPENDECTOMY	1 / 143	0.7%		0 / 138	0.0%		1.000
LAPAROTOMY	143 / 143	100.0%		138 / 138	100.0%		1.000
ABLATION ENDOMETRIOSIS	15 / 143	10.5%		18 / 138	13.0%		0.580
CYSTOTOMY REPAIR	1 / 143	0.7%		1 / 138	0.7%		1.000
OMENTECTOMY	0 / 143	0.0%		1 / 138	0.7%		0.491
LAPAROSCOPY	2 / 143	1.4%		4 / 138	2.9%		0.441
HYSEROSCOPY	7 / 143	4.9%		7 / 138	5.1%		1.000
HYSEROSCOPY / LYSIS	3 / 143	2.1%		0 / 138	0.0%		0.248
HYSEROSCOPY / RESECTION	1 / 143	0.7%		0 / 138	0.0%		1.000
EXCISION VAGINAL CYST	0 / 143	0.0%		1 / 138	0.7%		0.491
COLPOSCOPY	0 / 143	0.0%		1 / 138	0.7%		0.491
ENDOMETRIAL BIOPSY	1 / 143	0.7%		0 / 138	0.0%		1.000
DILATION AND CURETTAGE	3 / 143	2.1%		2 / 138	1.4%		1.000
MYOMECTIONY	96 / 143	67.1%		93 / 138	67.4%		1.000
CHROMOPERTUBATION	2 / 143	1.4%		7 / 138	5.1%		0.099
UTERINE SUSPENSION	2 / 143	1.4%		1 / 138	0.7%		0.491
UTERINE SUSPENSION / NEURECTOMY	0 / 143	0.0%		0 / 138	0.0%		1.000
SALPINGO-OOPHORECTOMY	1 / 143	0.7%		67 / 138	48.6%		0.905
ADHESIOLYSIS	71 / 143	49.7%		2 / 138	1.4%		1.000
TUBAL REVERSAL	3 / 143	2.1%		9 / 138	6.5%		0.435
FIMBRIOPLASTY	6 / 143	4.2%		13 / 138	9.4%		0.565
SALPINGOSTOMY	17 / 143	11.9%		4 / 138	2.9%		0.256
PARATUBAL CYSTECTOMY	9 / 143	6.3%		1 / 138	0.7%		0.371
OVARIAN RESECTION	4 / 143	2.8%		13 / 138	9.4%		0.843
OVARIAN CYSTECTOMY - SIMPLE	15 / 143	10.5%		11 / 138	8.0%		0.065
OVARIAN CYSTECTOMY - DERMID	4 / 143	2.8%		10 / 138	7.2%		0.524
OVARIAN CYSTECTOMY - ENDOMETRIOMA	14 / 143	9.8%		1 / 138	0.7%		0.491
OVARIAN SUSPENSION	0 / 143	0.0%					

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LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 4.2.2: Surgical Procedures - Patients Completing the Study

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
APPENDECTOMY	1 / 131	0.8%		0 / 134	0.0%		0.494
LAPAROTOMY	131 / 131	100.0%		134 / 134	100.0%		1.000
ABLATION ENDOMETRIOSIS	13 / 131	9.9%		18 / 134	13.4%		0.446
CYSTOTOMY REPAIR	1 / 131	0.8%		1 / 134	0.7%		1.000
OMENTECTOMY	0 / 131	0.0%		4 / 134	3.0%		0.684
LAPAROSCOPY	2 / 131	1.5%		6 / 134	4.5%		1.000
HYSTEROSCOPY	5 / 131	3.8%		0 / 134	0.0%		0.119
HYSTEROSCOPY / LYSIS	3 / 131	2.3%		0 / 134	0.0%		0.494
HYSIERSCOPY / RESECTION	1 / 131	0.8%		1 / 134	0.7%		1.000
EXCISION VAGINAL CYST	0 / 131	0.0%		1 / 134	0.7%		1.000
COLPOSCOPY	1 / 131	0.8%		0 / 134	0.0%		0.494
ENDOMETRIAL BIOPSY	3 / 131	2.3%		1 / 134	0.7%		0.367
DILATION AND CURETTAGE	88 / 131	67.2%		92 / 134	68.7%		0.895
MYOMECTIONY	2 / 131	1.5%		7 / 134	5.2%		0.172
CHROMOPERTUBATION	2 / 131	1.5%		1 / 134	0.7%		0.619
UTERINE SUSPENSION	2 / 131	1.5%		1 / 134	0.7%		1.000
UTERINE SUSPENSION / NEURECTOMY	0 / 131	0.0%		0 / 134	0.0%		0.494
SALPINGO-OOPHORECTOMY	1 / 131	0.8%		65 / 134	48.5%		0.806
ADHESIOLYSIS	66 / 131	50.4%		2 / 134	1.5%		1.000
TUBAL REVERSAL	2 / 131	1.5%		9 / 134	6.7%		0.255
FIMBRIOPLASTY	4 / 131	3.1%		13 / 134	9.7%		0.442
SALPINGOSTOMY	17 / 131	13.0%		4 / 134	3.0%		0.251
PARATUBAL CYSTECTOMY	8 / 131	6.1%		1 / 134	0.7%		0.210
OVARIAN RESECTION	4 / 131	3.1%		13 / 134	9.7%		1.000
OVARIAN CYSTECTOMY - SIMPLE	12 / 131	9.2%		8 / 134	6.0%		0.217
OVARIAN CYSTECTOMY - DERMID	3 / 131	2.3%		10 / 134	7.5%		0.519
OVARIAN CYSTECTOMY - ENDOMETRIOMA	13 / 131	9.9%		1 / 134	0.7%		1.000
OVARIAN SUSPENSION	0 / 131	0.0%					

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LIFECORE, INC.  
Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
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TABLE 4.2.3: Surgical Procedures - Patients with no Second Look

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
LAPAROTOMY	12	12	100.0%	4	4	100.0%	1.000
ABLATION ENDOMETRIOSIS	2	12	16.7%	0	4	0.0%	1.000
HYSEROSCOPY	2	12	16.7%	1	4	25.0%	1.000
DILATION AND CURETTAGE	0	12	0.0%	1	4	25.0%	0.250
MYOMECTION	8	12	66.7%	1	4	25.0%	0.262
ADHESIOLYSIS	5	12	41.7%	2	4	50.0%	1.000
TUBAL REVERSAL	1	12	8.3%	0	4	0.0%	1.000
FIMBRIOPLASTY	2	12	16.7%	0	4	0.0%	1.000
PARATUBAL CYSTECTOMY	1	12	8.3%	0	4	0.0%	0.529
OVARIAN CYSTECTOMY - SIMPLE	3	12	25.0%	3	4	75.0%	0.027
OVARIAN CYSTECTOMY - DERMID	1	12	8.3%	0	4	0.0%	1.000
OVARIAN CYSTECTOMY - ENDOMETRIOMA	1	12	8.3%				

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p values determined using the Fisher Exact test

LIFECORE, INC.  
Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
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TABLE 5.1.1.1: Adhesion Data -All Sites

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	131	3.65	(4.27)	0 to 15	134	3.46	(4.41)	0 to 14	0.727
Total Possible	131	22.82	(0.77)	18 to 23	134	22.66	(1.12)	18 to 23	0.157
Proportion	131	0.161	(0.187)	0.00 to 0.65	134	0.156	(0.201)	0.00 to 0.78	0.853
Severity Score(0-3)	131	0.38	(0.49)	0.0 to 1.9	134	0.35	(0.47)	0.0 to 1.7	0.517
Extent Score(0-3)	131	0.29	(0.39)	0.0 to 1.5	134	0.30	(0.40)	0.0 to 1.6	0.917
Modified AFS Score(0-16)	131	1.07	(1.67)	0.0 to 6.8	134	1.07	(1.70)	0.0 to 6.7	0.994
Adhesions Lysed	131	3.07	(3.84)	0 to 15	134	2.92	(4.05)	0 to 14	0.756
Surgical Sites	131	5.53	(3.46)	2 to 16	134	5.48	(3.55)	2 to 15	0.895
Mild Adhesions	131	1.11	(1.95)	0 to 8	134	1.37	(2.49)	0 to 11	0.348
Severe Adhesions	131	2.53	(3.54)	0 to 14	134	2.09	(3.14)	0 to 11	0.280
Localized Adhesions	131	1.50	(2.34)	0 to 10	134	1.25	(2.01)	0 to 9	0.351
Moderate Adhesions	131	1.34	(2.15)	0 to 9	134	1.35	(2.28)	0 to 10	0.957
Extensive Adhesions	131	0.82	(1.95)	0 to 8	134	0.87	(1.91)	0 to 9	0.837
<b>Second Look</b>									
Adhesions	131	6.38	(4.88)	0 to 18	134	7.72	(5.37)	0 to 22	0.034
Total Possible	131	23.24	(1.71)	16 to 24	134	23.04	(2.16)	13 to 24	0.405
Proportion	131	0.279	(0.215)	0.00 to 0.89	134	0.340	(0.237)	0.00 to 0.92	0.027
Severity Score(0-3)	131	0.51	(0.46)	0.0 to 1.9	134	0.76	(0.64)	0.0 to 2.7	0.001
Extent Score(0-3)	131	0.47	(0.45)	0.0 to 1.9	134	0.64	(0.58)	0.0 to 2.6	0.006
Modified AFS Score(0-16)	131	1.28	(1.55)	0.0 to 6.6	134	2.33	(2.70)	0.0 to 13.5	0.000

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**LIFECORE, INC.**  
**Lubricat Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.1.2: DeNovo, Surgical Site and Reformed Adhesions -All Sites

Variable	Lubricat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	131	4.80	(4.44)	0 to 18	134	5.72	(4.54)	0 to 19	0.098
Total Possible	131	20.18	(4.39)	9 to 24	134	20.13	(4.80)	5 to 24	0.931
Proportion	131	0.239	(0.206)	0.00 to 0.88	134	0.292	(0.227)	0.00 to 0.94	0.046
Severity Score	131	0.42	(0.42)	0.0 to 1.7	134	0.65	(0.61)	0.0 to 2.6	0.001
Extent Score	131	0.39	(0.41)	0.0 to 1.8	134	0.55	(0.54)	0.0 to 2.5	0.008
Modified AFS Score(0-16)	131	1.00	(1.30)	0.0 to 5.8	134	1.97	(2.51)	0.0 to 12.8	0.000
Surgical site Adhesions	131	2.49	(2.56)	0 to 12	134	3.23	(3.10)	0 to 13	0.035
Total Possible	131	6.39	(3.44)	1 to 17	134	6.35	(3.53)	3 to 16	0.928
Proportion	131	0.365	(0.304)	0.00 to 1.00	134	0.464	(0.293)	0.00 to 1.00	0.008
Severity Score(0-3)	131	0.73	(0.73)	0.0 to 3.0	134	1.04	(0.82)	0.0 to 3.0	0.001
Extent Score(0-3)	131	0.60	(0.62)	0.0 to 3.0	134	0.89	(0.73)	0.0 to 3.0	0.001
Modified AFS Score(0-16)	131	1.88	(2.51)	0.0 to 16.0	134	3.38	(3.73)	0.0 to 16.0	0.000
Surgical site DeNovo Adhesions	131	0.73	(0.86)	0 to 4	134	1.04	(1.01)	0 to 5	0.007
Total Possible	131	2.40	(0.98)	1 to 6	134	2.50	(1.10)	1 to 8	0.456
Proportion	131	0.290	(0.328)	0.00 to 1.00	134	0.389	(0.352)	0.00 to 1.00	0.018
Severity Score(0-3)	131	0.59	(0.82)	0.0 to 3.0	134	0.90	(0.97)	0.0 to 3.0	0.005
Extent Score(0-3)	131	0.45	(0.62)	0.0 to 3.0	134	0.72	(0.81)	0.0 to 3.0	0.003
Modified AFS Score(0-16)	131	1.41	(2.52)	0.0 to 16.0	134	2.79	(3.95)	0.0 to 16.0	0.001
Non-surgical site DeNovo Adhesions	131	4.08	(3.92)	0 to 16	134	4.68	(3.90)	0 to 17	0.211
Total Possible	131	17.77	(3.91)	8 to 22	134	17.63	(4.28)	4 to 22	0.775
Proportion	131	0.232	(0.210)	0.00 to 0.93	134	0.278	(0.229)	0.00 to 0.94	0.089
Severity Score(0-3)	131	0.40	(0.41)	0.0 to 1.6	134	0.61	(0.61)	0.0 to 2.6	0.001
Extent Score(0-3)	131	0.38	(0.42)	0.0 to 1.9	134	0.52	(0.54)	0.0 to 2.6	0.018
Modified AFS Score(0-16)	131	0.95	(1.27)	0.0 to 5.8	134	1.85	(2.49)	0.0 to 12.5	0.000
Reformed Adhesions	66	3.14	(2.69)	0 to 12	65	4.14	(3.32)	0 to 13	0.060
Total Possible	66	6.09	(3.29)	1 to 15	65	6.02	(3.90)	1 to 14	0.905
Proportion	66	0.492	(0.343)	0.00 to 1.00	65	0.690	(0.346)	0.00 to 1.00	0.001
Severity Score(0-3)	66	1.02	(0.84)	0.0 to 3.0	65	1.54	(1.05)	0.0 to 3.0	0.002
Extent Score(0-3)	66	0.88	(0.77)	0.0 to 2.7	65	1.37	(0.88)	0.0 to 3.0	0.001
Modified AFS Score(0-16)	66	2.87	(3.13)	0.0 to 12.0	65	5.06	(4.83)	0.0 to 16.0	0.002

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Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.2.1: Adhesion Data -Pelvic Sites

Variable	Lubricote Gel				Lactated Ringer's Solution				p
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	131	2.95	(3.78)	0 to 12	134	2.87	(3.81)	0 to 13	0.850
Total Possible	131	14.82	(0.77)	10 to 15	134	14.66	(1.12)	10 to 15	0.157
Proportion	131	0.200	(0.254)	0.00 to 0.80	134	0.202	(0.270)	0.00 to 1.00	0.955
Severity Score(0-3)	131	0.47	(0.65)	0.0 to 2.3	134	0.45	(0.63)	0.0 to 2.2	0.732
Extent Score(0-3)	131	0.36	(0.53)	0.0 to 2.1	134	0.39	(0.55)	0.0 to 2.0	0.717
Modified AFS Score(0-16)	131	1.37	(2.30)	0.0 to 9.9	134	1.45	(2.40)	0.0 to 9.8	0.795
Adhesions Lysed	131	2.53	(3.43)	0 to 12	134	2.47	(3.61)	0 to 13	0.896
Surgical Sites	131	3.97	(3.06)	1 to 12	134	4.00	(3.10)	1 to 13	0.936
Mild Adhesions	131	0.95	(1.77)	0 to 8	134	1.16	(2.22)	0 to 10	0.396
Severe Adhesions	131	2.01	(3.07)	0 to 11	134	1.71	(2.68)	0 to 10	0.400
Localized Adhesions	131	1.31	(2.22)	0 to 10	134	1.07	(1.83)	0 to 9	0.341
Moderate Adhesions	131	0.86	(1.79)	0 to 9	134	0.97	(1.89)	0 to 9	0.635
Extensive Adhesions	131	0.78	(1.83)	0 to 8	134	0.82	(1.81)	0 to 9	0.850
<b>Second Look</b>									
Adhesions	131	4.63	(3.74)	0 to 15	134	5.37	(4.06)	0 to 15	0.124
Total Possible	131	14.40	(1.39)	9 to 15	134	14.19	(1.89)	5 to 15	0.303
Proportion	131	0.329	(0.268)	0.00 to 1.00	134	0.391	(0.299)	0.00 to 1.00	0.077
Severity Score(0-3)	131	0.60	(0.57)	0.0 to 2.4	134	0.83	(0.77)	0.0 to 3.0	0.005
Extent Score(0-3)	131	0.55	(0.58)	0.0 to 2.4	134	0.74	(0.75)	0.0 to 3.0	0.021
Modified AFS Score(0-16)	131	1.58	(2.13)	0.0 to 9.4	134	2.71	(3.53)	0.0 to 16.0	0.002

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LIFECORE, INC.  
Lubricat Gel versus Lactated Ringer's solution for Prevention of Adhesions  
Protocol PTL-0013 and PTL-0022

TABLE 5.1.2.2: DeNovo, Surgical Site and Reformed Adhesions -Pelvic Sites

Variable	Lubricat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	131	3.27	(3.36)	0 to 15	133	3.70	(3.18)	0 to 13	0.293
Total Possible	131	11.87	(3.88)	3 to 15	133	11.81	(4.04)	2 to 15	0.905
Proportion	131	0.281	(0.266)	0.00 to 1.00	133	0.341	(0.300)	0.00 to 1.00	0.085
Severity Score	131	0.48	(0.51)	0.0 to 2.1	133	0.72	(0.75)	0.0 to 3.0	0.003
Extent Score	131	0.46	(0.54)	0.0 to 2.3	133	0.65	(0.75)	0.0 to 3.0	0.019
Modified AFS Score(0-16)	131	1.22	(1.85)	0.0 to 9.6	133	2.33	(3.51)	0.0 to 16.0	0.001
Surgical site Adhesions	129	1.98	(2.10)	0 to 10	134	2.51	(2.59)	0 to 12	0.074
Total Possible	129	3.98	(3.02)	1 to 12	134	3.94	(3.11)	1 to 13	0.923
Proportion	129	0.513	(0.399)	0.00 to 1.00	134	0.617	(0.373)	0.00 to 1.00	0.029
Severity Score(0-3)	129	1.01	(0.95)	0.0 to 3.0	134	1.36	(1.04)	0.0 to 3.0	0.005
Extent Score(0-3)	129	0.83	(0.79)	0.0 to 3.0	134	1.15	(0.90)	0.0 to 3.0	0.002
Modified AFS Score(0-16)	129	2.66	(3.42)	0.0 to 16.0	134	4.27	(4.66)	0.0 to 16.0	0.002
Surgical site DeNovo Adhesions	106	0.75	(0.77)	0 to 3	108	1.01	(0.81)	0 to 4	0.016
Total Possible	106	1.71	(0.76)	1 to 5	108	1.82	(0.88)	1 to 7	0.302
Proportion	106	0.465	(0.458)	0.00 to 1.00	108	0.570	(0.420)	0.00 to 1.00	0.083
Severity Score(0-3)	106	0.89	(1.08)	0.0 to 3.0	108	1.25	(1.12)	0.0 to 3.0	0.020
Extent Score(0-3)	106	0.67	(0.78)	0.0 to 3.0	108	1.02	(0.94)	0.0 to 3.0	0.004
Modified AFS Score(0-16)	106	2.01	(3.32)	0.0 to 16.0	108	3.65	(4.61)	0.0 to 16.0	0.003
Non-surgical site DeNovo Adhesions	131	2.67	(2.94)	0 to 13	133	2.88	(2.71)	0 to 12	0.550
Total Possible	131	10.49	(3.42)	3 to 14	133	10.33	(3.55)	2 to 14	0.714
Proportion	131	0.263	(0.269)	0.00 to 1.00	133	0.314	(0.305)	0.00 to 1.00	0.148
Severity Score(0-3)	131	0.44	(0.51)	0.0 to 2.1	133	0.66	(0.76)	0.0 to 3.0	0.007
Extent Score(0-3)	131	0.44	(0.56)	0.0 to 2.3	133	0.60	(0.75)	0.0 to 3.0	0.045
Modified AFS Score(0-16)	131	1.16	(1.89)	0.0 to 10.7	133	2.17	(3.50)	0.0 to 16.0	0.004
Reformed Adhesions	63	2.81	(2.39)	0 to 10	61	3.72	(2.92)	0 to 12	0.059
Total Possible	63	5.27	(3.16)	1 to 12	61	5.43	(3.54)	1 to 13	0.796
Proportion	63	0.552	(0.357)	0.00 to 1.00	61	0.714	(0.349)	0.00 to 1.00	0.012
Severity Score(0-3)	63	1.13	(0.91)	0.0 to 3.0	61	1.55	(1.05)	0.0 to 3.0	0.019
Extent Score(0-3)	63	0.98	(0.85)	0.0 to 3.0	61	1.44	(0.94)	0.0 to 3.0	0.005
Modified AFS Score(0-16)	63	3.26	(3.64)	0.0 to 12.0	61	5.34	(5.19)	0.0 to 16.0	0.011

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Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.3.1: Adhesion Data -General Surgical Sites

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	131	0.69	(1.16)	0 to 5	134	0.60	(1.00)	0 to 4	0.462
Total Possible	131	8.00	(0.00)	8 to 8	134	8.00	(0.00)	8 to 8	.
Proportion	131	0.087	(0.145)	0.00 to 0.63	134	0.075	(0.125)	0.00 to 0.50	0.462
Severity Score(0-3)	131	0.22	(0.39)	0.0 to 1.9	134	0.17	(0.30)	0.0 to 1.5	0.256
Extent Score(0-3)	131	0.16	(0.26)	0.0 to 1.0	134	0.13	(0.23)	0.0 to 1.0	0.465
Modified AFS Score(0-16)	131	0.53	(0.97)	0.0 to 3.6	134	0.43	(0.83)	0.0 to 4.0	0.355
Adhesions Lysed	131	0.54	(1.01)	0 to 5	134	0.45	(0.82)	0 to 4	0.404
Surgical Sites	131	1.56	(1.02)	1 to 6	134	1.48	(0.83)	1 to 5	0.444
Mild Adhesions	131	0.17	(0.53)	0 to 3	134	0.22	(0.62)	0 to 4	0.493
Severe Adhesions	131	0.53	(1.03)	0 to 5	134	0.38	(0.77)	0 to 4	0.191
Localized Adhesions	131	0.18	(0.49)	0 to 3	134	0.17	(0.47)	0 to 2	0.845
Moderate Adhesions	131	0.47	(0.92)	0 to 3	134	0.38	(0.76)	0 to 4	0.373
Extensive Adhesions	131	0.04	(0.19)	0 to 1	134	0.04	(0.21)	0 to 1	0.788
<b>Second Look</b>									
Adhesions	131	1.76	(1.67)	0 to 8	134	2.36	(1.99)	0 to 7	0.008
Total Possible	131	8.84	(0.51)	6 to 9	134	8.85	(0.43)	7 to 9	0.849
Proportion	131	0.199	(0.189)	0.00 to 0.89	134	0.268	(0.226)	0.00 to 0.88	0.008
Severity Score(0-3)	131	0.39	(0.45)	0.0 to 2.7	134	0.65	(0.65)	0.0 to 2.6	0.000
Extent Score(0-3)	131	0.33	(0.36)	0.0 to 1.8	134	0.50	(0.49)	0.0 to 2.0	0.001
Modified AFS Score(0-16)	131	0.84	(1.14)	0.0 to 8.0	134	1.80	(2.22)	0.0 to 9.8	0.000

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.3.2: DeNovo, Surgical Site and Reformed Adhesions -General Surgical Sites

Variable	Lubricote Gel				Lactated Ringer's Solution				p
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	131	1.53	(1.57)	0 to 8	134	2.04	(1.86)	0 to 7	0.015
Total Possible	131	8.31	(1.16)	4 to 9	134	8.40	(1.00)	5 to 9	0.462
Proportion	131	0.188	(0.189)	0.00 to 0.89	134	0.247	(0.221)	0.00 to 0.86	0.021
Severity Score	131	0.36	(0.44)	0.0 to 2.7	134	0.59	(0.64)	0.0 to 2.6	0.001
Extent Score	131	0.31	(0.35)	0.0 to 1.8	134	0.47	(0.49)	0.0 to 2.0	0.003
Modified AFS Score(0-16)	131	0.77	(1.12)	0.0 to 8.0	134	1.65	(2.23)	0.0 to 10.0	0.000
Surgical site Adhesions	131	0.53	(0.83)	0 to 3	134	0.72	(1.01)	0 to 5	0.097
Total Possible	131	2.47	(0.99)	1 to 7	134	2.41	(0.78)	1 to 5	0.565
Proportion	131	0.195	(0.300)	0.00 to 1.00	134	0.263	(0.328)	0.00 to 1.00	0.077
Severity Score(0-3)	131	0.39	(0.71)	0.0 to 3.0	134	0.65	(0.91)	0.0 to 3.0	0.009
Extent Score(0-3)	131	0.32	(0.57)	0.0 to 3.0	134	0.53	(0.76)	0.0 to 3.0	0.014
Modified AFS Score(0-16)	131	0.90	(2.10)	0.0 to 16.0	134	2.16	(3.77)	0.0 to 16.0	0.001
Surgical site DeNovo Adhesions	131	0.12	(0.33)	0 to 1	134	0.22	(0.44)	0 to 2	0.033
Total Possible	131	1.02	(0.15)	1 to 2	134	1.03	(0.17)	1 to 2	0.726
Proportion	131	0.122	(0.329)	0.00 to 1.00	134	0.216	(0.413)	0.00 to 1.00	0.041
Severity Score(0-3)	131	0.29	(0.85)	0.0 to 3.0	134	0.57	(1.15)	0.0 to 3.0	0.023
Extent Score(0-3)	131	0.24	(0.71)	0.0 to 3.0	134	0.45	(0.95)	0.0 to 3.0	0.047
Modified AFS Score(0-16)	131	0.83	(2.83)	0.0 to 16.0	134	2.07	(4.84)	0.0 to 16.0	0.012
Non-surgical site DeNovo Adhesions	131	1.40	(1.46)	0 to 7	134	1.82	(1.66)	0 to 6	0.031
Total Possible	131	7.28	(1.16)	3 to 8	134	7.37	(1.00)	4 to 8	0.496
Proportion	131	0.198	(0.202)	0.00 to 1.00	134	0.251	(0.223)	0.00 to 0.86	0.044
Severity Score(0-3)	131	0.37	(0.48)	0.0 to 3.0	134	0.59	(0.63)	0.0 to 2.5	0.002
Extent Score(0-3)	131	0.32	(0.36)	0.0 to 1.6	134	0.47	(0.48)	0.0 to 2.1	0.005
Modified AFS Score(0-16)	131	0.76	(1.10)	0.0 to 7.0	134	1.58	(2.12)	0.0 to 9.4	0.000
Reformed Adhesions	39	0.77	(0.81)	0 to 3	41	1.02	(0.94)	0 to 4	0.197
Total Possible	39	1.79	(1.06)	1 to 5	41	1.46	(0.84)	1 to 4	0.123
Proportion	39	0.454	(0.450)	0.00 to 1.00	41	0.675	(0.442)	0.00 to 1.00	0.030
Severity Score(0-3)	39	0.96	(1.12)	0.0 to 3.0	41	1.72	(1.29)	0.0 to 3.0	0.006
Extent Score(0-3)	39	0.77	(0.80)	0.0 to 2.0	41	1.24	(0.94)	0.0 to 3.0	0.018
Modified AFS Score(0-16)	39	2.16	(2.77)	0.0 to 8.0	41	4.52	(4.53)	0.0 to 16.0	0.007

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 Protocol PTL-0013 and PTL-0022

TABLE 5.1.4.1: Adhesion Data -Patients With Myomectomy

Variable	Lubricat Gel				Lactated Ringer's Solution				p
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	88	2.36	(3.54)	0 to 15	92	1.72	(2.97)	0 to 14	0.185
Total Possible	88	22.84	(0.80)	18 to 23	92	22.83	(0.78)	18 to 23	0.900
Proportion	88	0.104	(0.155)	0.00 to 0.65	92	0.077	(0.139)	0.00 to 0.78	0.227
Severity Score(0-3)	88	0.25	(0.41)	0.0 to 1.9	92	0.15	(0.28)	0.0 to 1.7	0.043
Extent Score(0-3)	88	0.18	(0.31)	0.0 to 1.4	92	0.13	(0.25)	0.0 to 1.6	0.228
Modified AFS Score(0-16)	88	0.69	(1.40)	0.0 to 6.5	92	0.41	(0.93)	0.0 to 5.8	0.117
Adhesions Lysed	88	1.94	(3.14)	0 to 15	92	1.42	(2.49)	0 to 10	0.220
Surgical Sites	88	4.58	(2.94)	2 to 16	92	4.22	(2.47)	2 to 12	0.371
Mild Adhesions	88	0.66	(1.49)	0 to 8	92	0.93	(2.31)	0 to 11	0.346
Severe Adhesions	88	1.70	(3.01)	0 to 14	92	0.78	(1.73)	0 to 9	0.012
Localized Adhesions	88	1.01	(1.93)	0 to 10	92	0.82	(1.80)	0 to 9	0.481
Moderate Adhesions	88	0.89	(1.72)	0 to 7	92	0.58	(1.24)	0 to 6	0.165
Extensive Adhesions	88	0.47	(1.48)	0 to 8	92	0.33	(1.03)	0 to 6	0.460
<b>Second Look</b>									
Adhesions	88	6.48	(4.95)	0 to 18	92	7.17	(5.39)	0 to 22	0.368
Total Possible	88	23.42	(1.50)	17 to 24	92	23.43	(1.67)	14 to 24	0.952
Proportion	88	0.279	(0.212)	0.00 to 0.75	92	0.310	(0.235)	0.00 to 0.92	0.350
Severity Score(0-3)	88	0.52	(0.47)	0.0 to 1.7	92	0.70	(0.65)	0.0 to 2.7	0.036
Extent Score(0-3)	88	0.46	(0.44)	0.0 to 1.7	92	0.59	(0.59)	0.0 to 2.6	0.083
Modified AFS Score(0-16)	88	1.30	(1.60)	0.0 to 6.5	92	2.23	(2.80)	0.0 to 13.5	0.007

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.4.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Myomectomy

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	88	5.40	(4.65)	0 to 18	92	6.14	(4.76)	0 to 19	0.291
Total Possible	88	21.48	(3.68)	9 to 24	92	22.01	(3.37)	5 to 24	0.311
Proportion	88	0.255	(0.206)	0.00 to 0.75	92	0.288	(0.231)	0.00 to 0.89	0.316
Severity Score	88	0.46	(0.44)	0.0 to 1.7	92	0.65	(0.64)	0.0 to 2.6	0.025
Extent Score	88	0.41	(0.41)	0.0 to 1.7	92	0.55	(0.57)	0.0 to 2.5	0.077
Modified AFS Score(0-16)	88	1.11	(1.41)	0.0 to 5.8	92	2.03	(2.71)	0.0 to 12.8	0.005
Surgical site Adhesions	88	2.09	(2.28)	0 to 12	92	2.40	(2.26)	0 to 12	0.359
Total Possible	88	5.47	(2.97)	1 to 17	92	5.13	(2.38)	3 to 13	0.403
Proportion	88	0.351	(0.297)	0.00 to 1.00	92	0.435	(0.297)	0.00 to 1.00	0.060
Severity Score(0-3)	88	0.72	(0.73)	0.0 to 3.0	92	0.99	(0.85)	0.0 to 3.0	0.025
Extent Score(0-3)	88	0.56	(0.57)	0.0 to 3.0	92	0.83	(0.75)	0.0 to 3.0	0.007
Modified AFS Score(0-16)	88	1.86	(2.54)	0.0 to 16.0	92	3.24	(3.91)	0.0 to 16.0	0.006
Surgical site DeNovo Adhesions	88	0.81	(0.83)	0 to 3	92	1.14	(0.97)	0 to 4	0.014
Total Possible	88	2.59	(0.92)	1 to 6	92	2.77	(0.97)	1 to 8	0.202
Proportion	88	0.310	(0.313)	0.00 to 1.00	92	0.401	(0.326)	0.00 to 1.00	0.058
Severity Score(0-3)	88	0.66	(0.82)	0.0 to 3.0	92	0.94	(0.93)	0.0 to 3.0	0.037
Extent Score(0-3)	88	0.49	(0.61)	0.0 to 3.0	92	0.73	(0.77)	0.0 to 3.0	0.021
Modified AFS Score(0-16)	88	1.69	(2.80)	0.0 to 16.0	92	2.90	(3.95)	0.0 to 16.0	0.019
Non-surgical site DeNovo Adhesions	88	4.59	(4.11)	0 to 16	92	5.00	(4.19)	0 to 17	0.509
Total Possible	88	18.89	(3.45)	8 to 22	92	19.24	(3.25)	4 to 22	0.480
Proportion	88	0.249	(0.210)	0.00 to 0.76	92	0.271	(0.234)	0.00 to 0.94	0.509
Severity Score(0-3)	88	0.44	(0.42)	0.0 to 1.5	92	0.60	(0.63)	0.0 to 2.6	0.042
Extent Score(0-3)	88	0.41	(0.41)	0.0 to 1.7	92	0.52	(0.57)	0.0 to 2.6	0.140
Modified AFS Score(0-16)	88	1.05	(1.36)	0.0 to 5.8	92	1.90	(2.67)	0.0 to 12.5	0.008
Reformed Adhesions	33	2.88	(2.69)	0 to 12	33	2.88	(2.38)	0 to 10	1.000
Total Possible	33	5.18	(3.08)	2 to 15	33	3.97	(2.70)	1 to 10	0.094
Proportion	33	0.501	(0.337)	0.00 to 1.00	33	0.682	(0.383)	0.00 to 1.00	0.045
Severity Score(0-3)	33	1.05	(0.84)	0.0 to 2.4	33	1.49	(1.14)	0.0 to 3.0	0.076
Extent Score(0-3)	33	0.87	(0.72)	0.0 to 2.3	33	1.40	(0.96)	0.0 to 3.0	0.014
Modified AFS Score(0-16)	33	2.90	(3.05)	0.0 to 9.6	33	5.15	(5.22)	0.0 to 16.0	0.036

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LIFECORE, INC.  
 Lubricoat Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.5.1: Adhesion Data -Patients Without Myomectomy

Variable	Lubricoat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	43	6.28	(4.47)	0 to 13	42	7.29	(4.66)	0 to 14	0.313
Total Possible	43	22.79	(0.71)	20 to 23	42	22.29	(1.58)	18 to 23	0.060
Proportion	43	0.276	(0.196)	0.00 to 0.57	42	0.328	(0.210)	0.00 to 0.61	0.239
Severity Score(0-3)	43	0.65	(0.52)	0.0 to 1.6	42	0.78	(0.52)	0.0 to 1.7	0.257
Extent Score(0-3)	43	0.51	(0.44)	0.0 to 1.5	42	0.65	(0.44)	0.0 to 1.4	0.141
Modified AFS Score(0-16)	43	1.86	(1.91)	0.0 to 6.8	42	2.52	(2.07)	0.0 to 6.7	0.131
Adhesions Lysed	43	5.37	(4.15)	0 to 13	42	6.19	(4.84)	0 to 14	0.405
Surgical Sites	43	7.49	(3.65)	2 to 14	42	8.24	(4.00)	2 to 15	0.369
Mild Adhesions	43	2.05	(2.42)	0 to 8	42	2.33	(2.61)	0 to 11	0.601
Severe Adhesions	43	4.23	(3.95)	0 to 12	42	4.95	(3.62)	0 to 11	0.384
Localized Adhesions	43	2.49	(2.79)	0 to 10	42	2.19	(2.13)	0 to 9	0.582
Moderate Adhesions	43	2.26	(2.64)	0 to 9	42	3.05	(3.03)	0 to 10	0.202
Extensive Adhesions	43	1.53	(2.54)	0 to 8	42	2.05	(2.71)	0 to 9	0.371
<b>Second Look</b>									
Adhesions	43	6.19	(4.78)	0 to 17	42	8.93	(5.17)	0 to 19	0.013
Total Possible	43	22.88	(2.04)	16 to 24	42	22.19	(2.79)	13 to 24	0.193
Proportion	43	0.278	(0.222)	0.00 to 0.89	42	0.407	(0.232)	0.00 to 0.90	0.011
Severity Score(0-3)	43	0.50	(0.45)	0.0 to 1.9	42	0.88	(0.62)	0.0 to 2.2	0.002
Extent Score(0-3)	43	0.48	(0.48)	0.0 to 1.9	42	0.75	(0.55)	0.0 to 2.1	0.016
Modified AFS Score(0-16)	43	1.25	(1.45)	0.0 to 6.6	42	2.55	(2.47)	0.0 to 10.5	0.004

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LIFECORE, INC.  
Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
Protocol PTL-0013 and PTL-0022

TABLE 5.1.5.2: DeNovo, Surgical Site and Reformed Adhesions -Patients Without Myomectomy

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	43	3.58	(3.74)	0 to 16	42	4.79	(3.90)	0 to 17	0.150
Total Possible	43	17.51	(4.57)	11 to 24	42	16.00	(4.90)	8 to 24	0.145
Proportion	43	0.207	(0.205)	0.00 to 0.88	42	0.303	(0.219)	0.00 to 0.94	0.040
Severity Score	43	0.34	(0.36)	0.0 to 1.6	42	0.64	(0.55)	0.0 to 2.1	0.003
Extent Score	43	0.35	(0.43)	0.0 to 1.8	42	0.56	(0.49)	0.0 to 1.9	0.032
Modified AFS Score(0-16)	43	0.77	(1.03)	0.0 to 5.3	42	1.83	(2.02)	0.0 to 8.2	0.003
Surgical site Adhesions	43	3.30	(2.92)	0 to 10	42	5.05	(3.86)	0 to 13	0.021
Total Possible	43	8.28	(3.60)	3 to 15	42	9.02	(4.16)	3 to 16	0.380
Proportion	43	0.393	(0.318)	0.00 to 1.00	42	0.526	(0.276)	0.00 to 1.00	0.043
Severity Score(0-3)	43	0.74	(0.75)	0.0 to 3.0	42	1.16	(0.76)	0.0 to 3.0	0.012
Extent Score(0-3)	43	0.68	(0.71)	0.0 to 3.0	42	1.01	(0.68)	0.0 to 2.8	0.031
Modified AFS Score(0-16)	43	1.91	(2.46)	0.0 to 9.3	42	3.67	(3.32)	0.0 to 14.7	0.007
Surgical site DeNovo Adhesions	43	0.56	(0.91)	0 to 4	42	0.81	(1.06)	0 to 5	0.244
Total Possible	43	2.02	(1.01)	1 to 5	42	1.90	(1.12)	1 to 5	0.610
Proportion	43	0.248	(0.359)	0.00 to 1.00	42	0.363	(0.406)	0.00 to 1.00	0.170
Severity Score(0-3)	43	0.45	(0.83)	0.0 to 3.0	42	0.83	(1.07)	0.0 to 3.0	0.069
Extent Score(0-3)	43	0.37	(0.62)	0.0 to 3.0	42	0.69	(0.91)	0.0 to 3.0	0.056
Modified AFS Score(0-16)	43	0.83	(1.71)	0.0 to 8.0	42	2.53	(3.98)	0.0 to 16.0	0.012
Non-surgical site DeNovo Adhesions	43	3.02	(3.30)	0 to 14	42	3.98	(3.13)	0 to 12	0.176
Total Possible	43	15.49	(3.86)	10 to 22	42	14.10	(4.18)	7 to 21	0.114
Proportion	43	0.197	(0.209)	0.00 to 0.93	42	0.294	(0.220)	0.00 to 0.92	0.041
Severity Score(0-3)	43	0.32	(0.36)	0.0 to 1.6	42	0.62	(0.57)	0.0 to 2.2	0.004
Extent Score(0-3)	43	0.34	(0.42)	0.0 to 1.9	42	0.54	(0.49)	0.0 to 2.0	0.039
Modified AFS Score(0-16)	43	0.75	(1.03)	0.0 to 5.4	42	1.73	(2.08)	0.0 to 9.3	0.007
Reformed Adhesions	33	3.39	(2.71)	0 to 9	32	5.44	(3.66)	0 to 13	0.013
Total Possible	33	7.00	(3.29)	1 to 13	32	8.13	(3.84)	1 to 14	0.209
Proportion	33	0.484	(0.354)	0.00 to 1.00	32	0.698	(0.309)	0.00 to 1.00	0.012
Severity Score(0-3)	33	0.99	(0.85)	0.0 to 3.0	32	1.58	(0.96)	0.0 to 3.0	0.011
Extent Score(0-3)	33	0.89	(0.82)	0.0 to 2.7	32	1.34	(0.81)	0.0 to 3.0	0.028
Modified AFS Score(0-16)	33	2.83	(3.26)	0.0 to 12.0	32	4.96	(4.48)	0.0 to 16.0	0.031

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LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.6.1: Adhesion Data - Patients With Adhesiolysis

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	66	7.11	(3.42)	1 to 15	65	6.94	(4.02)	1 to 14	0.798
Total Possible	66	22.73	(0.89)	18 to 23	65	22.46	(1.37)	18 to 23	0.189
Proportion	66	0.313	(0.149)	0.04 to 0.65	65	0.313	(0.187)	0.04 to 0.78	0.997
Severity Score(0-3)	66	0.75	(0.44)	0.0 to 1.9	65	0.69	(0.48)	0.0 to 1.7	0.449
Extent Score(0-3)	66	0.57	(0.38)	0.0 to 1.5	65	0.59	(0.40)	0.0 to 1.6	0.722
Modified AFS Score(0-16)	66	2.11	(1.84)	0.0 to 6.8	65	2.14	(1.92)	0.0 to 6.7	0.925
Adhesions Lysed	66	6.09	(3.29)	1 to 15	65	6.02	(3.90)	1 to 14	0.905
Surgical Sites	66	8.18	(2.99)	4 to 16	65	8.18	(3.33)	3 to 15	0.996
Mild Adhesions	66	2.18	(2.29)	0 to 8	65	2.83	(2.95)	0 to 11	0.161
Severe Adhesions	66	4.92	(3.62)	0 to 14	65	4.11	(3.47)	0 to 11	0.190
Localized Adhesions	66	2.88	(2.62)	0 to 10	65	2.51	(2.26)	0 to 9	0.388
Moderate Adhesions	66	2.61	(2.43)	0 to 9	65	2.68	(2.67)	0 to 10	0.874
Extensive Adhesions	66	1.62	(2.50)	0 to 8	65	1.75	(2.44)	0 to 9	0.759
<b>Second Look</b>									
Adhesions	66	7.23	(4.39)	0 to 17	65	9.23	(5.35)	0 to 22	0.021
Total Possible	66	22.71	(2.14)	16 to 24	65	22.54	(2.69)	13 to 24	0.683
Proportion	66	0.324	(0.202)	0.00 to 0.89	65	0.415	(0.239)	0.00 to 0.92	0.020
Severity Score(0-3)	66	0.62	(0.45)	0.0 to 1.9	65	0.93	(0.67)	0.0 to 2.7	0.002
Extent Score(0-3)	66	0.54	(0.42)	0.0 to 1.9	65	0.81	(0.60)	0.0 to 2.6	0.004
Modified AFS Score(0-16)	66	1.58	(1.56)	0.0 to 6.6	65	2.94	(2.91)	0.0 to 13.5	0.001

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LIFECORE, INC.  
 Lubricoat Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.6.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Adhesiolysis

Variable	Lubricoat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	66	4.09	(3.40)	0 to 14	65	5.09	(3.91)	0 to 17	0.120
Total Possible	66	16.62	(3.48)	9 to 23	65	16.52	(4.50)	5 to 23	0.889
Proportion	66	0.245	(0.195)	0.00 to 0.88	65	0.316	(0.238)	0.00 to 0.94	0.065
Severity Score	66	0.44	(0.38)	0.0 to 1.6	65	0.70	(0.64)	0.0 to 2.6	0.005
Extent Score	66	0.40	(0.36)	0.0 to 1.8	65	0.62	(0.58)	0.0 to 2.5	0.008
Modified AFS Score(0-16)	66	1.02	(1.11)	0.0 to 5.4	65	2.20	(2.67)	0.0 to 12.8	0.001
Surgical site Adhesions	66	3.80	(2.85)	0 to 12	65	4.98	(3.49)	0 to 13	0.035
Total Possible	66	8.97	(3.03)	5 to 17	65	8.95	(3.46)	4 to 16	0.978
Proportion	66	0.419	(0.282)	0.00 to 1.00	65	0.537	(0.273)	0.00 to 1.00	0.017
Severity Score(0-3)	66	0.87	(0.74)	0.0 to 3.0	65	1.21	(0.82)	0.0 to 3.0	0.015
Extent Score(0-3)	66	0.72	(0.57)	0.0 to 2.0	65	1.06	(0.69)	0.0 to 2.9	0.002
Modified AFS Score(0-16)	66	2.32	(2.41)	0.0 to 9.3	65	3.93	(3.64)	0.0 to 15.2	0.003
Surgical site DeNovo Adhesions	66	0.50	(0.64)	0 to 2	65	0.68	(0.77)	0 to 3	0.155
Total Possible	66	2.00	(0.93)	1 to 5	65	2.06	(1.22)	1 to 8	0.746
Proportion	66	0.239	(0.311)	0.00 to 1.00	65	0.315	(0.370)	0.00 to 1.00	0.205
Severity Score(0-3)	66	0.51	(0.84)	0.0 to 3.0	65	0.77	(1.05)	0.0 to 3.0	0.114
Extent Score(0-3)	66	0.37	(0.53)	0.0 to 2.0	65	0.60	(0.83)	0.0 to 3.0	0.056
Modified AFS Score(0-16)	66	1.13	(2.19)	0.0 to 10.0	65	2.32	(3.92)	0.0 to 16.0	0.034
Non-surgical site DeNovo Adhesions	66	3.59	(3.15)	0 to 14	65	4.42	(3.46)	0 to 16	0.157
Total Possible	66	14.62	(3.03)	8 to 20	65	14.46	(3.99)	4 to 21	0.797
Proportion	66	0.263	(0.204)	0.00 to 0.93	65	0.316	(0.242)	0.00 to 0.94	0.067
Severity Score(0-3)	66	0.43	(0.38)	0.0 to 1.6	65	0.69	(0.65)	0.0 to 2.6	0.005
Extent Score(0-3)	66	0.40	(0.38)	0.0 to 1.9	65	0.62	(0.59)	0.0 to 2.6	0.010
Modified AFS Score(0-16)	66	1.00	(1.15)	0.0 to 5.8	65	2.17	(2.70)	0.0 to 12.5	0.001
Reformed Adhesions	66	3.14	(2.69)	0 to 12	65	4.14	(3.32)	0 to 13	0.060
Total Possible	66	6.09	(3.29)	1 to 15	65	6.02	(3.90)	1 to 14	0.905
Proportion	66	0.492	(0.343)	0.00 to 1.00	65	0.690	(0.346)	0.00 to 1.00	0.001
Severity Score(0-3)	66	1.02	(0.84)	0.0 to 3.0	65	1.54	(1.05)	0.0 to 3.0	0.002
Extent Score(0-3)	66	0.88	(0.77)	0.0 to 2.7	65	1.37	(0.88)	0.0 to 3.0	0.001
Modified AFS Score(0-16)	66	2.87	(3.13)	0.0 to 12.0	65	5.06	(4.83)	0.0 to 16.0	0.002

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**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.7.1: Adhesion Data -Patients With Tubal Procedures

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Baseline Adhesions	20	8.15	(3.66)	0 to 13	20	10.00	(2.81)	2 to 14	0.081
Total Possible Proportion	20	22.50	(1.32)	18 to 23	20	22.25	(1.62)	18 to 23	0.595
	20	0.361	(0.156)	0.00 to 0.57	20	0.450	(0.130)	0.11 to 0.61	0.057
Severity Score(0-3)	20	0.84	(0.41)	0.0 to 1.5	20	1.02	(0.40)	0.3 to 1.7	0.166
Extent Score(0-3)	20	0.70	(0.42)	0.0 to 1.5	20	0.83	(0.29)	0.3 to 1.4	0.256
Modified AFS Score(0-16)	20	2.59	(1.88)	0.0 to 6.8	20	2.95	(1.78)	0.5 to 6.7	0.537
Adhesions Lysed Surgical Sites	20	7.45	(3.66)	0 to 13	20	9.65	(2.81)	2 to 14	0.040
	20	9.50	(3.20)	3 to 14	20	11.00	(2.71)	4 to 15	0.118
Mild Adhesions	20	2.75	(2.55)	0 to 8	20	3.70	(2.66)	0 to 10	0.256
Severe Adhesions	20	5.40	(3.23)	0 to 11	20	6.30	(3.18)	0 to 10	0.381
Localized Adhesions	20	3.00	(2.94)	0 to 10	20	3.65	(2.72)	0 to 9	0.472
Moderate Adhesions	20	2.75	(2.69)	0 to 9	20	4.40	(3.14)	0 to 10	0.082
Extensive Adhesions	20	2.40	(2.95)	0 to 8	20	1.95	(2.68)	0 to 9	0.616
Second Look Adhesions	20	6.50	(4.27)	0 to 15	20	10.25	(4.84)	2 to 18	0.013
Total Possible Proportion	20	22.80	(2.24)	17 to 24	20	22.90	(2.13)	16 to 24	0.886
	20	0.294	(0.199)	0.00 to 0.65	20	0.452	(0.219)	0.08 to 0.75	0.022
Severity Score(0-3)	20	0.57	(0.44)	0.0 to 1.5	20	1.04	(0.66)	0.1 to 2.2	0.012
Extent Score(0-3)	20	0.45	(0.33)	0.0 to 1.0	20	0.82	(0.59)	0.1 to 2.1	0.018
Modified AFS Score(0-16)	20	1.27	(1.22)	0.0 to 3.4	20	2.92	(3.02)	0.1 to 10.5	0.029

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

**TABLE 5.1.7.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Tubal Procedures**

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	20	2.70	(2.68)	0 to 9	20	4.05	(3.19)	0 to 13	0.155
Total Possible	20	15.35	(3.53)	11 to 24	20	13.25	(2.88)	8 to 18	0.046
Proportion	20	0.181	(0.184)	0.00 to 0.64	20	0.308	(0.223)	0.00 to 0.76	0.056
Severity Score	20	0.32	(0.39)	0.0 to 1.2	20	0.73	(0.61)	0.0 to 1.8	0.015
Extent Score	20	0.27	(0.26)	0.0 to 0.8	20	0.59	(0.53)	0.0 to 1.8	0.019
Modified AFS Score(0-16)	20	0.68	(0.85)	0.0 to 2.7	20	2.16	(2.40)	0.0 to 8.2	0.013
Surgical site Adhesions	20	4.25	(2.88)	0 to 10	20	6.80	(3.50)	1 to 13	0.016
Total Possible	20	10.35	(3.27)	4 to 15	20	11.95	(2.76)	5 to 16	0.103
Proportion	20	0.414	(0.246)	0.00 to 0.83	20	0.562	(0.250)	0.07 to 1.00	0.066
Severity Score(0-3)	20	0.82	(0.56)	0.0 to 1.7	20	1.26	(0.80)	0.1 to 3.0	0.051
Extent Score(0-3)	20	0.64	(0.48)	0.0 to 1.8	20	0.98	(0.71)	0.1 to 2.8	0.080
Modified AFS Score(0-16)	20	1.93	(1.86)	0.0 to 6.2	20	3.51	(3.87)	0.1 to 14.7	0.110
Surgical site DeNovo Adhesions	20	0.40	(0.60)	0 to 2	20	0.55	(0.69)	0 to 2	0.466
Total Possible	20	2.00	(0.97)	1 to 4	20	1.35	(0.67)	1 to 3	0.019
Proportion	20	0.167	(0.242)	0.00 to 0.67	20	0.367	(0.441)	0.00 to 1.00	0.083
Severity Score(0-3)	20	0.28	(0.54)	0.0 to 2.0	20	0.98	(1.29)	0.0 to 3.0	0.031
Extent Score(0-3)	20	0.27	(0.42)	0.0 to 1.3	20	0.59	(0.83)	0.0 to 3.0	0.126
Modified AFS Score(0-16)	20	0.68	(1.67)	0.0 to 6.7	20	2.46	(4.00)	0.0 to 16.0	0.075
Non-surgical site DeNovo Adhesions	20	2.30	(2.49)	0 to 9	20	3.50	(2.72)	0 to 11	0.154
Total Possible	20	13.35	(2.92)	10 to 21	20	11.90	(2.71)	7 to 17	0.112
Proportion	20	0.177	(0.196)	0.00 to 0.69	20	0.302	(0.232)	0.00 to 0.79	0.073
Severity Score(0-3)	20	0.32	(0.39)	0.0 to 1.3	20	0.71	(0.63)	0.0 to 2.0	0.024
Extent Score(0-3)	20	0.27	(0.26)	0.0 to 0.8	20	0.60	(0.57)	0.0 to 2.0	0.022
Modified AFS Score(0-16)	20	0.67	(0.80)	0.0 to 2.4	20	2.14	(2.56)	0.0 to 9.3	0.019
Reformed Adhesions	19	4.00	(2.69)	0 to 9	20	6.20	(3.11)	1 to 12	0.024
Total Possible	19	7.84	(3.30)	3 to 13	20	9.65	(2.81)	2 to 14	0.073
Proportion	19	0.531	(0.318)	0.00 to 1.00	20	0.659	(0.271)	0.08 to 1.00	0.185
Severity Score(0-3)	19	1.09	(0.75)	0.0 to 2.3	20	1.43	(0.84)	0.1 to 3.0	0.188
Extent Score(0-3)	19	0.84	(0.65)	0.0 to 2.3	20	1.12	(0.74)	0.1 to 3.0	0.209
Modified AFS Score(0-16)	19	2.63	(2.65)	0.0 to 8.8	20	3.85	(4.20)	0.1 to 16.0	0.286

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.B.1: Adhesion Data -Patients With Ovarian Procedures

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Baseline									
Adhesions	31	6.35	(4.56)	0 to 12	33	5.42	(4.55)	0 to 13	0.417
Total Possible	31	22.94	(0.36)	21 to 23	33	22.21	(1.65)	18 to 23	0.020
Proportion	31	0.278	(0.199)	0.00 to 0.52	33	0.249	(0.213)	0.00 to 0.61	0.579
Severity Score(0-3)	31	0.66	(0.55)	0.0 to 1.6	33	0.61	(0.54)	0.0 to 1.7	0.714
Extent Score(0-3)	31	0.51	(0.44)	0.0 to 1.3	33	0.51	(0.47)	0.0 to 1.4	0.992
Modified AFS Score(0-16)	31	1.86	(1.95)	0.0 to 5.9	33	2.03	(2.12)	0.0 to 6.7	0.747
Adhesions Lysed	31	5.16	(4.01)	0 to 12	33	4.06	(4.23)	0 to 13	0.290
Surgical Sites	31	7.48	(3.61)	3 to 13	33	6.79	(3.49)	2 to 14	0.436
Mild Adhesions	31	2.00	(2.37)	0 to 8	33	1.55	(1.86)	0 to 7	0.394
Severe Adhesions	31	4.35	(4.28)	0 to 12	33	3.88	(3.55)	0 to 11	0.629
Localized Adhesions	31	2.48	(2.71)	0 to 10	33	1.45	(1.46)	0 to 5	0.061
Moderate Adhesions	31	2.42	(2.71)	0 to 9	33	2.27	(2.76)	0 to 10	0.831
Extensive Adhesions	31	1.45	(2.34)	0 to 7	33	1.70	(2.52)	0 to 8	0.688
Second Look									
Adhesions	31	7.06	(4.55)	0 to 17	33	9.00	(5.01)	0 to 19	0.112
Total Possible	31	22.77	(2.16)	16 to 24	33	21.85	(3.07)	13 to 24	0.171
Proportion	31	0.318	(0.216)	0.00 to 0.89	33	0.420	(0.231)	0.00 to 0.90	0.074
Severity Score(0-3)	31	0.57	(0.46)	0.0 to 1.9	33	0.90	(0.64)	0.0 to 2.2	0.020
Extent Score(0-3)	31	0.58	(0.50)	0.0 to 1.9	33	0.80	(0.56)	0.0 to 2.1	0.110
Modified AFS Score(0-16)	31	1.53	(1.64)	0.0 to 6.6	33	2.66	(2.45)	0.0 to 10.5	0.035

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**LIFECORE, INC.**  
**Lubricat Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.8.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Ovarian Procedures

Variable	Lubricat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	31	4.23	(3.96)	0 to 16	33	5.76	(3.79)	0 to 17	0.119
Total Possible	31	17.58	(4.62)	12 to 24	33	17.79	(5.12)	8 to 24	0.866
Proportion	31	0.238	(0.204)	0.00 to 0.88	33	0.366	(0.219)	0.00 to 0.94	0.045
Severity Score	31	0.40	(0.36)	0.0 to 1.6	33	0.71	(0.56)	0.0 to 2.1	0.011
Extent Score	31	0.43	(0.46)	0.0 to 1.8	33	0.64	(0.52)	0.0 to 1.9	0.094
Modified AFS Score(0-16)	31	1.00	(1.12)	0.0 to 5.3	33	1.98	(2.12)	0.0 to 8.2	0.025
Surgical site Adhesions	31	3.61	(2.93)	0 to 10	33	4.61	(3.44)	0 to 13	0.219
Total Possible	31	8.32	(3.48)	4 to 14	33	7.52	(3.62)	3 to 15	0.367
Proportion	31	0.419	(0.304)	0.00 to 1.00	33	0.562	(0.248)	0.00 to 1.00	0.044
Severity Score(0-3)	31	0.76	(0.71)	0.0 to 3.0	33	1.24	(0.74)	0.0 to 2.4	0.010
Extent Score(0-3)	31	0.76	(0.72)	0.0 to 3.0	33	1.11	(0.65)	0.0 to 2.5	0.045
Modified AFS Score(0-16)	31	2.06	(2.49)	0.0 to 9.3	33	3.97	(3.17)	0.0 to 11.7	0.010
Surgical site DeNovo Adhesions	31	0.61	(1.02)	0 to 4	33	1.18	(1.18)	0 to 5	0.045
Total Possible	31	2.19	(1.08)	1 to 5	33	2.55	(1.18)	1 to 5	0.217
Proportion	31	0.253	(0.375)	0.00 to 1.00	33	0.396	(0.345)	0.00 to 1.00	0.115
Severity Score(0-3)	31	0.47	(0.84)	0.0 to 3.0	33	0.79	(0.79)	0.0 to 3.0	0.123
Extent Score(0-3)	31	0.40	(0.70)	0.0 to 3.0	33	0.73	(0.77)	0.0 to 2.7	0.085
Modified AFS Score(0-16)	31	0.95	(1.88)	0.0 to 8.0	33	2.25	(2.88)	0.0 to 10.7	0.037
Non-surgical site DeNovo Adhesions	31	3.61	(3.44)	0 to 14	33	4.58	(2.93)	0 to 12	0.232
Total Possible	31	15.39	(3.93)	10 to 21	33	15.24	(4.41)	7 to 21	0.890
Proportion	31	0.233	(0.206)	0.00 to 0.93	33	0.333	(0.221)	0.00 to 0.92	0.068
Severity Score(0-3)	31	0.39	(0.35)	0.0 to 1.6	33	0.69	(0.57)	0.0 to 2.2	0.016
Extent Score(0-3)	31	0.42	(0.45)	0.0 to 1.9	33	0.61	(0.51)	0.0 to 2.0	0.137
Modified AFS Score(0-16)	31	1.00	(1.12)	0.0 to 5.4	33	1.87	(2.12)	0.0 to 9.3	0.046
Reformed Adhesions	24	3.67	(2.85)	0 to 9	22	4.86	(3.43)	1 to 13	0.203
Total Possible	24	6.71	(3.24)	1 to 12	22	6.09	(3.79)	1 to 13	0.555
Proportion	24	0.510	(0.359)	0.00 to 1.00	22	0.809	(0.217)	0.29 to 1.00	0.001
Severity Score(0-3)	24	1.01	(0.87)	0.0 to 3.0	22	1.89	(0.92)	0.5 to 3.0	0.002
Extent Score(0-3)	24	0.98	(0.84)	0.0 to 2.7	22	1.70	(0.63)	0.4 to 3.0	0.002
Modified AFS Score(0-16)	24	3.03	(3.40)	0.0 to 12.0	22	6.26	(4.21)	1.0 to 16.0	0.006

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.9.1: Adhesion Data -Patients With Dermoid or Endometrioma Ovarian Procedures

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	16	5.63	(3.95)	0 to 12	18	4.28	(4.27)	0 to 11	0.348
Total Possible	16	23.00	(0.00)	23 to 23	18	22.22	(1.66)	18 to 23	0.071
Proportion	16	0.245	(0.172)	0.00 to 0.52	18	0.196	(0.198)	0.00 to 0.48	0.450
Severity Score(0-3)	16	0.60	(0.53)	0.0 to 1.6	18	0.48	(0.49)	0.0 to 1.2	0.473
Extent Score(0-3)	16	0.42	(0.34)	0.0 to 1.2	18	0.40	(0.43)	0.0 to 1.1	0.912
Modified AFS Score(0-16)	16	1.51	(1.62)	0.0 to 5.7	18	1.59	(1.92)	0.0 to 5.6	0.898
Adhesions Lysed	16	4.50	(3.31)	0 to 10	18	2.44	(3.01)	0 to 11	0.067
Surgical Sites	16	7.00	(3.16)	3 to 13	18	5.72	(2.89)	3 to 14	0.227
Mild Adhesions	16	1.50	(2.07)	0 to 7	18	1.22	(1.63)	0 to 5	0.664
Severe Adhesions	16	4.13	(4.30)	0 to 12	18	3.06	(3.24)	0 to 8	0.416
Localized Adhesions	16	2.38	(2.53)	0 to 8	18	1.17	(1.25)	0 to 4	0.081
Moderate Adhesions	16	2.50	(2.88)	0 to 9	18	1.72	(2.08)	0 to 7	0.369
Extensive Adhesions	16	0.75	(1.44)	0 to 5	18	1.39	(2.12)	0 to 6	0.317
<b>Second Look</b>									
Adhesions	16	6.69	(5.10)	0 to 17	18	8.44	(5.44)	0 to 19	0.340
Total Possible	16	22.94	(1.73)	19 to 24	18	21.39	(3.26)	13 to 24	0.099
Proportion	16	0.303	(0.253)	0.00 to 0.89	18	0.408	(0.256)	0.00 to 0.90	0.235
Severity Score(0-3)	16	0.51	(0.51)	0.0 to 1.9	18	0.77	(0.61)	0.0 to 2.0	0.177
Extent Score(0-3)	16	0.53	(0.55)	0.0 to 1.9	18	0.81	(0.61)	0.0 to 2.0	0.178
Modified AFS Score(0-16)	16	1.32	(1.76)	0.0 to 6.6	18	2.45	(2.32)	0.0 to 7.8	0.122

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.9.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Dermoid or Endometrioma Ovarian Procedures

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	16	4.56	(4.07)	0 to 14	18	6.44	(4.53)	0 to 17	0.214
Total Possible	16	18.38	(3.95)	12 to 24	18	18.94	(4.81)	11 to 24	0.711
Proportion	16	0.249	(0.233)	0.00 to 0.88	18	0.367	(0.254)	0.00 to 0.94	0.171
Severity Score	16	0.39	(0.41)	0.0 to 1.6	18	0.68	(0.58)	0.0 to 2.1	0.102
Extent Score	16	0.41	(0.49)	0.0 to 1.8	18	0.70	(0.58)	0.0 to 1.9	0.125
Modified AFS Score(0-16)	16	0.89	(1.30)	0.0 to 5.3	18	2.04	(2.17)	0.0 to 7.1	0.074
Surgical site Adhesions	16	3.00	(2.94)	0 to 10	18	3.78	(2.88)	0 to 11	0.442
Total Possible	16	7.81	(2.86)	4 to 12	18	6.39	(2.93)	4 to 15	0.162
Proportion	16	0.407	(0.351)	0.00 to 1.00	18	0.537	(0.260)	0.00 to 1.00	0.224
Severity Score(0-3)	16	0.72	(0.84)	0.0 to 3.0	18	1.04	(0.68)	0.0 to 2.3	0.234
Extent Score(0-3)	16	0.68	(0.69)	0.0 to 2.0	18	1.13	(0.70)	0.0 to 2.5	0.068
Modified AFS Score(0-16)	16	1.84	(2.67)	0.0 to 9.3	18	3.81	(3.14)	0.0 to 10.3	0.060
Surgical site DeNovo Adhesions	16	0.69	(1.01)	0 to 3	18	1.61	(1.24)	0 to 5	0.025
Total Possible	16	2.31	(1.20)	1 to 5	18	3.06	(0.87)	1 to 5	0.045
Proportion	16	0.281	(0.393)	0.00 to 1.00	18	0.491	(0.306)	0.00 to 1.00	0.091
Severity Score(0-3)	16	0.51	(0.86)	0.0 to 3.0	18	0.90	(0.68)	0.0 to 2.2	0.152
Extent Score(0-3)	16	0.33	(0.46)	0.0 to 1.0	18	1.00	(0.84)	0.0 to 2.7	0.008
Modified AFS Score(0-16)	16	0.77	(1.38)	0.0 to 4.0	18	3.22	(3.40)	0.0 to 10.7	0.011
Non-surgical site DeNovo Adhesions	16	3.88	(3.77)	0 to 14	18	4.83	(3.49)	0 to 12	0.447
Total Possible	16	16.06	(3.26)	11 to 21	18	15.89	(4.51)	9 to 21	0.900
Proportion	16	0.242	(0.242)	0.00 to 0.93	18	0.342	(0.250)	0.00 to 0.92	0.245
Severity Score(0-3)	16	0.37	(0.39)	0.0 to 1.6	18	0.64	(0.59)	0.0 to 2.2	0.134
Extent Score(0-3)	16	0.41	(0.51)	0.0 to 1.9	18	0.64	(0.53)	0.0 to 1.8	0.221
Modified AFS Score(0-16)	16	0.89	(1.33)	0.0 to 5.4	18	1.78	(1.97)	0.0 to 6.2	0.135
Reformed Adhesions	13	2.62	(2.84)	0 to 9	10	3.60	(2.37)	1 to 9	0.387
Total Possible	13	5.62	(2.75)	1 to 10	10	4.40	(2.76)	1 to 11	0.306
Proportion	13	0.445	(0.431)	0.00 to 1.00	10	0.828	(0.176)	0.50 to 1.00	0.015
Severity Score(0-3)	13	0.83	(0.97)	0.0 to 3.0	10	1.59	(0.85)	0.5 to 3.0	0.062
Extent Score(0-3)	13	0.91	(1.00)	0.0 to 2.7	10	1.86	(0.61)	1.0 to 3.0	0.016
Modified AFS Score(0-16)	13	2.62	(3.67)	0.0 to 12.0	10	6.02	(4.68)	1.0 to 16.0	0.064

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**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

**TABLE 5.1.10.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Dermoid Ovarian Procedures**

Variable	Lubricote Gel			Lactated Ringer's Solution			P		
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions									
Total Possible	3	3.00	(1.73)	1 to 4	8	6.50	(5.61)	0 to 17	0.329
Proportion	3	21.67	(4.04)	17 to 24	8	21.38	(3.85)	13 to 24	0.914
Severity Score	3	0.131	(0.062)	0.06 to 0.17	8	0.326	(0.270)	0.00 to 0.71	0.260
Extent Score	3	0.17	(0.01)	0.2 to 0.2	8	0.65	(0.56)	0.0 to 1.6	0.189
Modified AFS Score(0-16)	3	0.14	(0.08)	0.1 to 0.2	8	0.60	(0.54)	0.0 to 1.6	0.199
	3	0.20	(0.03)	0.2 to 0.2	8	1.88	(1.91)	0.0 to 5.9	0.175
Surgical site Adhesions									
Total Possible	3	1.67	(0.58)	1 to 2	8	3.50	(3.59)	0 to 11	0.416
Proportion	3	6.00	(3.46)	4 to 10	8	6.13	(3.87)	4 to 15	0.962
Severity Score(0-3)	3	0.367	(0.231)	0.10 to 0.50	8	0.498	(0.326)	0.00 to 1.00	0.543
Extent Score(0-3)	3	0.43	(0.12)	0.3 to 0.5	8	1.03	(0.75)	0.0 to 2.3	0.214
Modified AFS Score(0-16)	3	0.43	(0.12)	0.3 to 0.5	8	1.02	(0.76)	0.0 to 2.5	0.233
	3	0.87	(0.64)	0.5 to 1.6	8	3.67	(3.17)	0.0 to 10.2	0.175
Surgical site DeNovo Adhesions									
Total Possible	3	1.33	(1.15)	0 to 2	8	1.88	(1.46)	0 to 5	0.581
Proportion	3	2.67	(0.58)	2 to 3	8	3.38	(0.74)	3 to 5	0.175
Severity Score(0-3)	3	0.444	(0.385)	0.00 to 0.67	8	0.521	(0.301)	0.00 to 1.00	0.734
Extent Score(0-3)	3	0.44	(0.38)	0.0 to 0.7	8	1.13	(0.69)	0.0 to 2.2	0.146
Modified AFS Score(0-16)	3	0.44	(0.38)	0.0 to 0.7	8	1.03	(0.77)	0.0 to 2.6	0.245
	3	0.44	(0.38)	0.0 to 0.7	8	4.12	(3.39)	0.0 to 10.6	0.104
Non-surgical site DeNovo Adhesions									
Total Possible	3	1.67	(0.58)	1 to 2	8	4.63	(4.27)	0 to 12	0.277
Proportion	3	19.00	(3.46)	15 to 21	8	18.00	(3.74)	10 to 21	0.698
Severity Score(0-3)	3	0.086	(0.016)	0.07 to 0.10	8	0.288	(0.263)	0.00 to 0.63	0.230
Extent Score(0-3)	3	0.13	(0.06)	0.1 to 0.2	8	0.55	(0.54)	0.0 to 1.5	0.225
Modified AFS Score(0-16)	3	0.10	(0.04)	0.1 to 0.1	8	0.51	(0.51)	0.0 to 1.3	0.208
	3	0.17	(0.09)	0.1 to 0.3	8	1.44	(1.61)	0.0 to 4.6	0.219
Reformed Adhesions									
Total Possible	1	1.00	.	1 to 1	2	5.50	(4.95)	2 to 9	0.593
Proportion	1	7.00	.	7 to 7	2	7.00	(5.66)	3 to 11	1.000
Severity Score(0-3)	1	0.143	.	0.14 to 0.14	2	0.742	(0.107)	0.67 to 0.82	0.137
Extent Score(0-3)	1	0.43	.	0.4 to 0.4	2	1.29	(0.88)	0.7 to 1.9	0.571
Modified AFS Score(0-16)	1	0.43	.	0.4 to 0.4	2	1.82	(0.26)	1.6 to 2.0	0.142
	1	2.29	.	2.3 to 2.3	2	4.11	(2.04)	2.7 to 5.5	0.598

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LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.11.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Endometrioma Ovarian Procedures

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions									
Total Possible	13	4.92	(4.41)	0 to 14	10	6.40	(3.78)	2 to 15	0.407
Proportion	13	17.62	(3.66)	12 to 24	10	17.00	(4.76)	11 to 24	0.729
Severity Score	13	0.276	(0.251)	0.00 to 0.88	10	0.399	(0.251)	0.13 to 0.94	0.257
Extent Score	13	0.44	(0.44)	0.0 to 1.6	10	0.71	(0.63)	0.1 to 2.1	0.234
Modified AFS Score(0-16)	13	0.47	(0.52)	0.0 to 1.8	10	0.79	(0.62)	0.1 to 1.9	0.200
	13	1.05	(1.41)	0.0 to 5.3	10	2.18	(2.45)	0.1 to 7.1	0.179
Surgical site Adhesions									
Total Possible	13	3.31	(3.20)	0 to 10	10	4.00	(2.36)	1 to 8	0.572
Proportion	13	8.23	(2.68)	4 to 12	10	6.60	(2.12)	4 to 10	0.129
Severity Score(0-3)	13	0.416	(0.380)	0.00 to 1.00	10	0.568	(0.206)	0.25 to 0.89	0.267
Extent Score(0-3)	13	0.79	(0.92)	0.0 to 3.0	10	1.05	(0.67)	0.3 to 2.3	0.466
Modified AFS Score(0-16)	13	0.74	(0.76)	0.0 to 2.0	10	1.22	(0.68)	0.3 to 2.3	0.126
	13	2.07	(2.93)	0.0 to 9.3	10	3.92	(3.28)	0.3 to 10.3	0.169
Surgical site DeNovo Adhesions									
Total Possible	13	0.54	(0.97)	0 to 3	10	1.40	(1.07)	0 to 3	0.057
Proportion	13	2.23	(1.30)	1 to 5	10	2.80	(0.92)	1 to 4	0.254
Severity Score(0-3)	13	0.244	(0.400)	0.00 to 1.00	10	0.467	(0.324)	0.00 to 1.00	0.166
Extent Score(0-3)	13	0.53	(0.95)	0.0 to 3.0	10	0.72	(0.65)	0.0 to 2.0	0.593
Modified AFS Score(0-16)	13	0.31	(0.48)	0.0 to 1.0	10	0.98	(0.93)	0.0 to 2.7	0.036
	13	0.85	(1.52)	0.0 to 4.0	10	2.50	(3.41)	0.0 to 10.7	0.132
Non-surgical site DeNovo Adhesions									
Total Possible	13	4.38	(4.03)	0 to 14	10	5.00	(2.94)	2 to 12	0.689
Proportion	13	15.38	(2.93)	11 to 21	10	14.20	(4.52)	9 to 20	0.454
Severity Score(0-3)	13	0.278	(0.256)	0.00 to 0.93	10	0.385	(0.245)	0.10 to 0.92	0.321
Extent Score(0-3)	13	0.43	(0.42)	0.0 to 1.6	10	0.71	(0.64)	0.1 to 2.2	0.218
Modified AFS Score(0-16)	13	0.49	(0.55)	0.0 to 1.9	10	0.74	(0.56)	0.1 to 1.8	0.288
	13	1.05	(1.44)	0.0 to 5.4	10	2.06	(2.26)	0.1 to 6.2	0.207
Reformed Adhesions									
Total Possible	12	2.75	(2.93)	0 to 9	8	3.13	(1.55)	1 to 5	0.745
Proportion	12	5.50	(2.84)	1 to 10	8	3.75	(1.67)	1 to 6	0.136
Severity Score(0-3)	12	0.470	(0.440)	0.00 to 1.00	8	0.850	(0.189)	0.50 to 1.00	0.035
Extent Score(0-3)	12	0.86	(1.01)	0.0 to 3.0	8	1.67	(0.88)	0.5 to 3.0	0.082
Modified AFS Score(0-16)	12	0.95	(1.04)	0.0 to 2.7	8	1.87	(0.68)	1.0 to 3.0	0.042
	12	2.65	(3.83)	0.0 to 12.0	8	6.50	(5.13)	1.0 to 16.0	0.070

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LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.12.1: Adhesion Data -Patients With Endometriosis Excision

Variable	Lubricote Gel			Lactated Ringer's Solution			P		
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Baseline									
Adhesions	13	4.85	(5.26)	0 to 15	18	2.94	(4.02)	0 to 13	0.263
Total Possible	13	22.31	(1.49)	18 to 23	18	23.00	(0.00)	23 to 23	0.057
Proportion	13	0.215	(0.232)	0.00 to 0.65	18	0.128	(0.175)	0.00 to 0.57	0.241
Severity Score(0-3)	13	0.52	(0.65)	0.0 to 1.9	18	0.21	(0.33)	0.0 to 1.1	0.094
Extent Score(0-3)	13	0.39	(0.48)	0.0 to 1.4	18	0.26	(0.37)	0.0 to 1.2	0.384
Modified AFS Score(0-16)	13	1.43	(2.20)	0.0 to 6.5	18	0.72	(1.41)	0.0 to 5.0	0.280
Adhesions Lysed	13	3.85	(4.58)	0 to 15	18	2.44	(3.78)	0 to 13	0.359
Surgical Sites	13	7.00	(3.81)	3 to 16	18	6.00	(3.18)	3 to 14	0.433
Mild Adhesions	13	1.38	(2.10)	0 to 7	18	1.94	(2.96)	0 to 11	0.565
Severe Adhesions	13	3.46	(4.89)	0 to 14	18	1.00	(2.11)	0 to 7	0.066
Localized Adhesions	13	1.69	(2.36)	0 to 6	18	0.67	(0.97)	0 to 3	0.106
Moderate Adhesions	13	2.31	(2.63)	0 to 7	18	1.61	(2.57)	0 to 9	0.466
Extensive Adhesions	13	0.85	(2.08)	0 to 6	18	0.67	(1.85)	0 to 7	0.802
Second Look									
Adhesions	13	7.85	(4.86)	1 to 18	18	8.39	(5.84)	0 to 18	0.787
Total Possible	13	22.38	(2.33)	17 to 24	18	23.50	(1.47)	18 to 24	0.112
Proportion	13	0.351	(0.209)	0.05 to 0.75	18	0.354	(0.241)	0.00 to 0.75	0.965
Severity Score(0-3)	13	0.65	(0.53)	0.1 to 1.7	18	0.69	(0.58)	0.0 to 2.2	0.838
Extent Score(0-3)	13	0.60	(0.49)	0.1 to 1.7	18	0.67	(0.55)	0.0 to 1.8	0.723
Modified AFS Score(0-16)	13	1.72	(2.10)	0.1 to 6.5	18	2.22	(2.38)	0.0 to 8.9	0.550

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

**TABLE 5.1.12.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Endometriosis Excision**

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	13	5.54	(4.37)	0 to 18	18	6.56	(5.52)	0 to 18	0.586
Total Possible	13	18.46	(5.25)	9 to 24	18	21.06	(4.02)	11 to 24	0.130
Proportion	13	0.295	(0.187)	0.00 to 0.75	18	0.302	(0.230)	0.00 to 0.75	0.924
Severity Score	13	0.52	(0.41)	0.0 to 1.5	18	0.60	(0.59)	0.0 to 2.2	0.657
Extent Score	13	0.51	(0.42)	0.0 to 1.7	18	0.59	(0.55)	0.0 to 1.8	0.659
Modified AFS Score(0-16)	13	1.34	(1.55)	0.0 to 5.8	18	1.96	(2.45)	0.0 to 8.9	0.425
Surgical site Adhesions	13	3.46	(3.20)	1 to 12	18	3.00	(3.24)	0 to 13	0.697
Total Possible	13	7.92	(3.86)	4 to 17	18	6.50	(3.31)	4 to 15	0.280
Proportion	13	0.408	(0.226)	0.13 to 0.75	18	0.442	(0.280)	0.00 to 0.87	0.727
Severity Score(0-3)	13	0.70	(0.56)	0.1 to 1.9	18	0.84	(0.75)	0.0 to 2.4	0.574
Extent Score(0-3)	13	0.66	(0.48)	0.1 to 1.6	18	0.87	(0.71)	0.0 to 2.4	0.343
Modified AFS Score(0-16)	13	1.72	(2.19)	0.1 to 7.6	18	2.88	(3.46)	0.0 to 12.8	0.296
Surgical site DeNovo Adhesions	13	1.08	(0.76)	0 to 2	18	1.00	(0.97)	0 to 3	0.814
Total Possible	13	3.08	(1.32)	1 to 6	18	3.28	(1.60)	1 to 8	0.714
Proportion	13	0.342	(0.267)	0.00 to 0.67	18	0.294	(0.301)	0.00 to 1.00	0.648
Severity Score(0-3)	13	0.47	(0.45)	0.0 to 1.3	18	0.60	(0.72)	0.0 to 2.3	0.558
Extent Score(0-3)	13	0.50	(0.44)	0.0 to 1.3	18	0.61	(0.77)	0.0 to 2.7	0.641
Modified AFS Score(0-16)	13	0.94	(1.52)	0.0 to 5.7	18	2.15	(3.30)	0.0 to 12.0	0.232
Non-surgical site DeNovo Adhesions	13	4.46	(3.91)	0 to 16	18	5.56	(4.82)	0 to 16	0.506
Total Possible	13	15.38	(4.29)	8 to 21	18	17.78	(3.32)	10 to 21	0.090
Proportion	13	0.285	(0.201)	0.00 to 0.76	18	0.300	(0.234)	0.00 to 0.76	0.848
Severity Score(0-3)	13	0.52	(0.43)	0.0 to 1.5	18	0.59	(0.60)	0.0 to 2.2	0.726
Extent Score(0-3)	13	0.51	(0.44)	0.0 to 1.7	18	0.58	(0.55)	0.0 to 2.0	0.707
Modified AFS Score(0-16)	13	1.41	(1.59)	0.0 to 5.8	18	1.89	(2.52)	0.0 to 9.6	0.545
Reformed Adhesions	8	3.75	(3.92)	0 to 12	10	3.30	(4.35)	0 to 13	0.823
Total Possible	8	6.38	(4.34)	2 to 15	10	4.40	(4.17)	1 to 13	0.341
Proportion	8	0.459	(0.365)	0.00 to 1.00	10	0.590	(0.423)	0.00 to 1.00	0.498
Severity Score(0-3)	8	0.88	(0.90)	0.0 to 2.2	10	0.94	(0.95)	0.0 to 3.0	0.886
Extent Score(0-3)	8	0.77	(0.72)	0.0 to 1.9	10	0.95	(0.77)	0.0 to 2.3	0.622
Modified AFS Score(0-16)	8	2.26	(3.11)	0.0 to 8.7	10	2.57	(3.75)	0.0 to 12.0	0.853

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.13.1: Adhesion Data -Patients With Endometriosis Excision or Endometrioma Ovarian Procedures

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	24	5.42	(4.63)	0 to 15	26	4.23	(4.29)	0 to 13	0.352
Total Possible	24	22.63	(1.13)	18 to 23	26	22.65	(1.09)	18 to 23	0.927
Proportion	24	0.238	(0.203)	0.00 to 0.65	26	0.191	(0.195)	0.00 to 0.57	0.404
Severity Score(0-3)	24	0.59	(0.60)	0.0 to 1.9	26	0.40	(0.45)	0.0 to 1.2	0.207
Extent Score(0-3)	24	0.42	(0.42)	0.0 to 1.4	26	0.39	(0.43)	0.0 to 1.2	0.801
Modified AFS Score(0-16)	24	1.59	(1.99)	0.0 to 6.5	26	1.37	(1.88)	0.0 to 5.6	0.689
Adhesions Lysed	24	4.33	(4.02)	0 to 15	26	2.81	(3.32)	0 to 13	0.149
Surgical Sites	24	7.13	(3.48)	3 to 16	26	6.12	(2.82)	3 to 14	0.264
Mild Adhesions	24	1.38	(1.86)	0 to 7	26	1.92	(2.64)	0 to 11	0.404
Severe Adhesions	24	4.04	(4.68)	0 to 14	26	2.31	(3.03)	0 to 8	0.123
Localized Adhesions	24	2.13	(2.47)	0 to 8	26	1.12	(1.21)	0 to 4	0.070
Moderate Adhesions	24	2.38	(2.73)	0 to 9	26	1.81	(2.38)	0 to 9	0.437
Extensive Adhesions	24	0.92	(1.86)	0 to 6	26	1.31	(2.26)	0 to 7	0.509
<b>Second Look</b>									
Adhesions	24	7.79	(5.00)	0 to 18	26	8.88	(5.41)	0 to 19	0.463
Total Possible	24	22.58	(2.06)	17 to 24	26	22.23	(3.02)	13 to 24	0.635
Proportion	24	0.353	(0.236)	0.00 to 0.89	26	0.406	(0.242)	0.00 to 0.90	0.436
Severity Score(0-3)	24	0.64	(0.53)	0.0 to 1.9	26	0.78	(0.60)	0.0 to 2.2	0.399
Extent Score(0-3)	24	0.63	(0.54)	0.0 to 1.9	26	0.80	(0.58)	0.0 to 2.0	0.277
Modified AFS Score(0-16)	24	1.72	(2.01)	0.0 to 6.6	26	2.54	(2.47)	0.0 to 8.9	0.208

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

**TABLE 5.1.13.2: DeNovo, Surgical Site and Reformed Adhesions -Patients With Endometriosis Excision or Endometrioma Ovarian Procedures**

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	24	5.38	(4.34)	0 to 18	26	6.69	(5.03)	0 to 18	0.328
Total Possible	24	18.21	(4.60)	9 to 24	26	19.42	(4.78)	11 to 24	0.365
Proportion	24	0.292	(0.217)	0.00 to 0.88	26	0.349	(0.262)	0.00 to 0.94	0.391
Severity Score	24	0.50	(0.42)	0.0 to 1.6	26	0.67	(0.61)	0.0 to 2.2	0.263
Extent Score	24	0.50	(0.47)	0.0 to 1.8	26	0.69	(0.59)	0.0 to 1.9	0.221
Modified AFS Score(0-16)	24	1.25	(1.50)	0.0 to 5.8	26	2.12	(2.47)	0.0 to 8.9	0.142
Surgical site Adhesions	24	3.38	(3.19)	0 to 12	26	3.50	(3.01)	0 to 13	0.887
Total Possible	24	7.96	(3.34)	4 to 17	26	6.69	(2.95)	4 to 15	0.161
Proportion	24	0.418	(0.313)	0.00 to 1.00	26	0.499	(0.265)	0.00 to 0.89	0.328
Severity Score(0-3)	24	0.78	(0.77)	0.0 to 3.0	26	0.95	(0.73)	0.0 to 2.4	0.440
Extent Score(0-3)	24	0.72	(0.64)	0.0 to 2.0	26	1.04	(0.71)	0.0 to 2.4	0.106
Modified AFS Score(0-16)	24	2.02	(2.61)	0.0 to 9.3	26	3.36	(3.45)	0.0 to 12.8	0.129
Surgical site DeNovo Adhesions	24	0.79	(0.88)	0 to 3	26	1.15	(1.05)	0 to 3	0.194
Total Possible	24	2.67	(1.40)	1 to 6	26	3.08	(1.44)	1 to 8	0.314
Proportion	24	0.290	(0.337)	0.00 to 1.00	26	0.361	(0.327)	0.00 to 1.00	0.454
Severity Score(0-3)	24	0.51	(0.75)	0.0 to 3.0	26	0.65	(0.71)	0.0 to 2.3	0.500
Extent Score(0-3)	24	0.39	(0.46)	0.0 to 1.3	26	0.75	(0.86)	0.0 to 2.7	0.074
Modified AFS Score(0-16)	24	0.93	(1.54)	0.0 to 5.7	26	2.28	(3.37)	0.0 to 12.0	0.078
Non-surgical site DeNovo Adhesions	24	4.58	(3.94)	0 to 16	26	5.54	(4.29)	0 to 16	0.418
Total Possible	24	15.54	(3.71)	8 to 21	26	16.35	(4.19)	9 to 21	0.477
Proportion	24	0.290	(0.227)	0.00 to 0.93	26	0.343	(0.241)	0.00 to 0.92	0.426
Severity Score(0-3)	24	0.49	(0.43)	0.0 to 1.6	26	0.66	(0.62)	0.0 to 2.2	0.278
Extent Score(0-3)	24	0.51	(0.49)	0.0 to 1.9	26	0.67	(0.56)	0.0 to 2.0	0.304
Modified AFS Score(0-16)	24	1.29	(1.54)	0.0 to 5.8	26	2.05	(2.45)	0.0 to 9.6	0.199
Reformed Adhesions	18	3.22	(3.44)	0 to 12	17	3.35	(3.37)	0 to 13	0.910
Total Possible	18	5.83	(3.62)	1 to 15	17	4.29	(3.24)	1 to 13	0.195
Proportion	18	0.475	(0.419)	0.00 to 1.00	17	0.688	(0.359)	0.00 to 1.00	0.116
Severity Score(0-3)	18	0.92	(0.98)	0.0 to 3.0	17	1.28	(1.00)	0.0 to 3.0	0.290
Extent Score(0-3)	18	0.93	(0.94)	0.0 to 2.7	17	1.38	(0.87)	0.0 to 3.0	0.151
Modified AFS Score(0-16)	18	2.72	(3.60)	0.0 to 12.0	17	4.51	(4.79)	0.0 to 16.0	0.219

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

**TABLE 5.1.14.1: Adhesion Data -Sites With Endometriosis**

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	23	1.78	(2.35)	0 to 8	29	1.52	(2.06)	0 to 9	0.667
Total Possible	23	3.30	(2.46)	1 to 8	29	3.10	(2.43)	1 to 10	0.769
Proportion	23	0.496	(0.477)	0.00 to 1.00	29	0.414	(0.438)	0.00 to 1.00	0.517
Severity Score(0-3)	23	1.26	(1.37)	0.0 to 3.0	29	0.89	(1.02)	0.0 to 3.0	0.264
Extent Score(0-3)	23	0.89	(0.92)	0.0 to 2.6	29	0.87	(1.00)	0.0 to 3.0	0.951
Modified AFS Score(0-16)	23	3.21	(3.99)	0.0 to 13.0	29	3.00	(4.26)	0.0 to 16.0	0.858
Adhesions Lysed	23	1.30	(1.66)	0 to 6	29	1.21	(1.93)	0 to 9	0.849
Surgical Sites	23	2.48	(1.90)	0 to 8	29	2.62	(1.72)	1 to 9	0.778
Mild Adhesions	23	0.22	(0.52)	0 to 2	29	0.45	(0.78)	0 to 3	0.229
Severe Adhesions	23	1.57	(2.43)	0 to 8	29	1.07	(1.71)	0 to 6	0.392
Localized Adhesions	23	0.52	(1.08)	0 to 4	29	0.34	(0.61)	0 to 2	0.461
Moderate Adhesions	23	0.87	(1.10)	0 to 3	29	0.55	(0.91)	0 to 4	0.259
Extensive Adhesions	23	0.39	(1.20)	0 to 5	29	0.62	(1.24)	0 to 4	0.503
<b>Second Look</b>									
Adhesions	23	1.26	(1.51)	0 to 6	29	1.69	(1.85)	0 to 9	0.374
Total Possible	23	2.87	(2.12)	1 to 7	29	2.79	(2.21)	1 to 9	0.900
Proportion	23	0.511	(0.462)	0.00 to 1.00	29	0.656	(0.425)	0.00 to 1.00	0.246
Severity Score(0-3)	23	0.89	(1.01)	0.0 to 3.0	29	1.29	(1.14)	0.0 to 3.0	0.193
Extent Score(0-3)	23	0.88	(0.99)	0.0 to 3.0	29	1.42	(1.19)	0.0 to 3.0	0.084
Modified AFS Score(0-16)	23	2.03	(2.90)	0.0 to 11.3	29	4.85	(5.90)	0.0 to 16.0	0.041

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LIFECORE, INC.  
 Lubricoat Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.14.2: DeNovo, Surgical Site and Reformed Adhesions -Sites With Endometriosis

Variable	Lubricoat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	14	0.79	(0.70)	0 to 2	21	0.76	(0.70)	0 to 2	0.922
Total Possible	14	2.50	(2.07)	1 to 7	21	2.19	(1.97)	1 to 9	0.658
Proportion	14	0.487	(0.473)	0.00 to 1.00	21	0.521	(0.483)	0.00 to 1.00	0.838
Severity Score	14	0.77	(1.03)	0.0 to 3.0	21	0.95	(1.13)	0.0 to 3.0	0.642
Extent Score	14	0.67	(0.75)	0.0 to 2.0	21	1.12	(1.23)	0.0 to 3.0	0.230
Modified AFS Score(0-16)	14	1.31	(2.23)	0.0 to 8.0	21	3.24	(4.94)	0.0 to 16.0	0.182
Surgical site Adhesions	22	1.18	(1.56)	0 to 6	29	1.66	(1.84)	0 to 9	0.337
Total Possible	22	2.55	(1.63)	1 to 6	29	2.52	(1.81)	1 to 9	0.954
Proportion	22	0.523	(0.475)	0.00 to 1.00	29	0.666	(0.415)	0.00 to 1.00	0.257
Severity Score(0-3)	22	0.92	(1.02)	0.0 to 3.0	29	1.30	(1.13)	0.0 to 3.0	0.216
Extent Score(0-3)	22	0.91	(1.01)	0.0 to 3.0	29	1.44	(1.18)	0.0 to 3.0	0.097
Modified AFS Score(0-16)	22	2.11	(2.94)	0.0 to 11.3	29	4.89	(5.89)	0.0 to 16.0	0.048
Surgical site DeNovo Adhesions	13	0.62	(0.65)	0 to 2	20	0.75	(0.72)	0 to 2	0.589
Total Possible	13	1.85	(0.99)	1 to 4	20	1.80	(1.11)	1 to 5	0.904
Proportion	13	0.500	(0.500)	0.00 to 1.00	20	0.517	(0.474)	0.00 to 1.00	0.924
Severity Score(0-3)	13	0.81	(1.07)	0.0 to 3.0	20	0.87	(1.04)	0.0 to 3.0	0.876
Extent Score(0-3)	13	0.69	(0.78)	0.0 to 2.0	20	1.09	(1.26)	0.0 to 3.0	0.308
Modified AFS Score(0-16)	13	1.38	(2.30)	0.0 to 8.0	20	3.02	(4.93)	0.0 to 16.0	0.275
Non-surgical site DeNovo Adhesions	5	0.60	(0.89)	0 to 2	3	0.33	(0.58)	0 to 1	0.665
Total Possible	5	2.20	(1.64)	1 to 5	3	3.33	(3.21)	1 to 7	0.523
Proportion	5	0.180	(0.249)	0.00 to 0.50	3	0.333	(0.577)	0.00 to 1.00	0.610
Severity Score(0-3)	5	0.18	(0.25)	0.0 to 0.5	3	1.00	(1.73)	0.0 to 3.0	0.313
Extent Score(0-3)	5	0.18	(0.25)	0.0 to 0.5	3	0.67	(1.15)	0.0 to 2.0	0.376
Modified AFS Score(0-16)	5	0.18	(0.25)	0.0 to 0.5	3	2.67	(4.62)	0.0 to 8.0	0.250
Reformed Adhesions	13	1.38	(1.71)	0 to 6	14	2.36	(2.17)	1 to 9	0.210
Total Possible	13	2.38	(1.56)	1 to 6	14	2.50	(2.14)	1 to 9	0.875
Proportion	13	0.531	(0.479)	0.00 to 1.00	14	0.940	(0.155)	0.50 to 1.00	0.005
Severity Score(0-3)	13	1.03	(1.07)	0.0 to 3.0	14	2.02	(1.01)	0.5 to 3.0	0.020
Extent Score(0-3)	13	1.07	(1.16)	0.0 to 3.0	14	2.08	(0.92)	0.5 to 3.0	0.019
Modified AFS Score(0-16)	13	2.84	(3.49)	0.0 to 11.3	14	8.11	(6.49)	0.5 to 16.0	0.015

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.15.1: Adhesion Data -Sites Without Endometriosis

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	131	3.34	(3.99)	0 to 14	134	3.13	(4.23)	0 to 14	0.690
Total Possible	131	22.24	(1.78)	15 to 23	134	21.99	(2.06)	13 to 23	0.275
Proportion	131	0.152	(0.178)	0.00 to 0.64	134	0.147	(0.199)	0.00 to 0.78	0.830
Severity Score(0-3)	131	0.36	(0.45)	0.0 to 1.8	134	0.32	(0.47)	0.0 to 1.8	0.529
Extent Score(0-3)	131	0.27	(0.37)	0.0 to 1.5	134	0.28	(0.39)	0.0 to 1.6	0.969
Modified AFS Score(0-16)	131	1.00	(1.57)	0.0 to 6.8	134	0.98	(1.66)	0.0 to 6.7	0.948
Adhesions Lysed	131	2.84	(3.67)	0 to 14	134	2.66	(3.91)	0 to 14	0.695
Surgical Sites	131	5.10	(3.30)	2 to 15	134	4.91	(3.51)	1 to 15	0.652
Mild Adhesions	131	1.08	(1.90)	0 to 8	134	1.28	(2.37)	0 to 11	0.451
Severe Adhesions	131	2.26	(3.17)	0 to 13	134	1.86	(3.02)	0 to 11	0.292
Localized Adhesions	131	1.40	(2.22)	0 to 10	134	1.17	(2.00)	0 to 9	0.370
Moderate Adhesions	131	1.18	(1.93)	0 to 9	134	1.23	(2.15)	0 to 10	0.848
Extensive Adhesions	131	0.75	(1.88)	0 to 8	134	0.73	(1.77)	0 to 9	0.941
<b>Second Look</b>									
Adhesions	131	6.16	(4.80)	0 to 17	134	7.36	(5.20)	0 to 22	0.052
Total Possible	131	22.74	(2.28)	14 to 24	134	22.44	(2.81)	11 to 24	0.341
Proportion	131	0.274	(0.212)	0.00 to 0.88	134	0.334	(0.234)	0.00 to 0.92	0.031
Severity Score(0-3)	131	0.50	(0.46)	0.0 to 1.9	134	0.74	(0.64)	0.0 to 2.7	0.001
Extent Score(0-3)	131	0.46	(0.44)	0.0 to 1.8	134	0.63	(0.56)	0.0 to 2.6	0.007
Modified AFS Score(0-16)	131	1.25	(1.53)	0.0 to 6.6	134	2.27	(2.67)	0.0 to 13.5	0.000

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LIFECORE, INC.  
Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
Protocol PTL-0013 and PTL-0022

TABLE 5.1.15.2: DeNovo, Surgical Site and Reformed Adhesions -Sites Without Endometriosis

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	131	4.72	(4.42)	0 to 17	134	5.60	(4.46)	0 to 19	0.108
Total Possible	131	19.91	(4.45)	9 to 24	134	19.78	(4.89)	5 to 24	0.828
Proportion	131	0.237	(0.206)	0.00 to 0.88	134	0.291	(0.225)	0.00 to 0.93	0.045
Severity Score	131	0.42	(0.42)	0.0 to 1.7	134	0.64	(0.61)	0.0 to 2.6	0.001
Extent Score	131	0.39	(0.41)	0.0 to 1.8	134	0.55	(0.54)	0.0 to 2.5	0.009
Modified AFS Score(0-16)	131	1.00	(1.31)	0.0 to 6.0	134	1.96	(2.50)	0.0 to 12.8	0.000
Surgical site Adhesions	131	2.29	(2.41)	0 to 11	134	2.87	(2.95)	0 to 13	0.079
Total Possible	131	5.96	(3.32)	1 to 16	134	5.81	(3.51)	1 to 16	0.711
Proportion	131	0.356	(0.299)	0.00 to 1.00	134	0.443	(0.305)	0.00 to 1.00	0.020
Severity Score(0-3)	131	0.71	(0.73)	0.0 to 3.0	134	1.01	(0.84)	0.0 to 3.0	0.002
Extent Score(0-3)	131	0.58	(0.60)	0.0 to 3.0	134	0.84	(0.75)	0.0 to 3.0	0.002
Modified AFS Score(0-16)	131	1.82	(2.48)	0.0 to 16.0	134	3.23	(3.79)	0.0 to 16.0	0.000
Surgical site DeNovo Adhesions	131	0.66	(0.84)	0 to 4	134	0.93	(0.96)	0 to 5	0.019
Total Possible	131	2.22	(0.88)	1 to 6	134	2.23	(0.95)	1 to 6	0.929
Proportion	131	0.275	(0.326)	0.00 to 1.00	134	0.375	(0.362)	0.00 to 1.00	0.019
Severity Score(0-3)	131	0.57	(0.82)	0.0 to 3.0	134	0.90	(1.00)	0.0 to 3.0	0.004
Extent Score(0-3)	131	0.43	(0.62)	0.0 to 3.0	134	0.69	(0.82)	0.0 to 3.0	0.003
Modified AFS Score(0-16)	131	1.38	(2.55)	0.0 to 16.0	134	2.80	(4.07)	0.0 to 16.0	0.001
Non-surgical site DeNovo Adhesions	131	4.05	(3.92)	0 to 16	134	4.67	(3.91)	0 to 17	0.200
Total Possible	131	17.69	(3.93)	8 to 22	134	17.55	(4.35)	4 to 22	0.792
Proportion	131	0.231	(0.210)	0.00 to 0.93	134	0.278	(0.228)	0.00 to 0.94	0.084
Severity Score(0-3)	131	0.40	(0.41)	0.0 to 1.6	134	0.61	(0.61)	0.0 to 2.6	0.001
Extent Score(0-3)	131	0.38	(0.42)	0.0 to 1.9	134	0.52	(0.54)	0.0 to 2.6	0.018
Modified AFS Score(0-16)	131	0.95	(1.27)	0.0 to 5.8	134	1.84	(2.49)	0.0 to 12.5	0.000
Reformed Adhesions	66	2.86	(2.54)	0 to 11	63	3.75	(3.19)	0 to 12	0.084
Total Possible	66	5.62	(3.30)	1 to 14	63	5.65	(3.96)	1 to 14	0.963
Proportion	66	0.486	(0.343)	0.00 to 1.00	63	0.654	(0.371)	0.00 to 1.00	0.008
Severity Score(0-3)	66	1.01	(0.86)	0.0 to 3.0	63	1.46	(1.06)	0.0 to 3.0	0.009
Extent Score(0-3)	66	0.86	(0.75)	0.0 to 2.5	63	1.27	(0.88)	0.0 to 3.0	0.005
Modified AFS Score(0-16)	66	2.79	(3.14)	0.0 to 12.0	63	4.62	(4.64)	0.0 to 16.0	0.009

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.16.1: Adhesion Data -Sites With Sutures

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Baseline Adhesions	122	0.48	(0.85)	0 to 4	116	0.48	(0.92)	0 to 4	0.949
Total Possible Proportion	122	1.85	(0.75)	1 to 5	116	1.91	(0.90)	1 to 5	0.623
Severity Score(0-3)	122	0.238	(0.386)	0.00 to 1.00	116	0.215	(0.374)	0.00 to 1.00	0.631
Extent Score(0-3)	122	0.56	(0.98)	0.0 to 3.0	116	0.50	(0.94)	0.0 to 3.0	0.671
Modified AFS Score(0-16)	122	0.44	(0.81)	0.0 to 3.0	116	0.40	(0.74)	0.0 to 3.0	0.714
Adhesions Lysed Surgical Sites	122	1.54	(3.40)	0.0 to 16.0	116	1.38	(2.86)	0.0 to 16.0	0.699
Mild Adhesions	122	0.43	(0.83)	0 to 4	116	0.45	(0.90)	0 to 4	0.902
Severe Adhesions	122	2.85	(0.75)	2 to 6	116	2.91	(0.90)	2 to 6	0.623
Localized Adhesions	122	0.18	(0.59)	0 to 4	116	0.17	(0.50)	0 to 3	0.911
Moderate Adhesions	122	0.30	(0.61)	0 to 3	116	0.31	(0.69)	0 to 4	0.857
Extensive Adhesions	122	0.19	(0.52)	0 to 3	116	0.15	(0.40)	0 to 2	0.488
Moderate Adhesions	122	0.17	(0.49)	0 to 3	116	0.23	(0.57)	0 to 2	0.378
Extensive Adhesions	122	0.11	(0.41)	0 to 3	116	0.10	(0.36)	0 to 2	0.821
Second Look Adhesions	131	1.01	(1.00)	0 to 4	134	1.28	(1.19)	0 to 5	0.042
Total Possible Proportion	131	2.69	(0.88)	1 to 6	134	2.62	(1.07)	1 to 6	0.533
Severity Score(0-3)	131	0.354	(0.322)	0.00 to 1.00	134	0.441	(0.350)	0.00 to 1.00	0.036
Extent Score(0-3)	131	0.73	(0.82)	0.0 to 3.0	134	1.02	(0.97)	0.0 to 3.0	0.010
Modified AFS Score(0-16)	131	0.60	(0.68)	0.0 to 3.0	134	0.83	(0.84)	0.0 to 3.0	0.015
	131	1.96	(2.87)	0.0 to 16.0	134	3.27	(4.29)	0.0 to 16.0	0.004

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LIFECORE, INC.  
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Protocol PTL-0013 and PTL-0022

TABLE 5.1.16.2: DeNovo, Surgical Site and Reformed Adhesions -Sites With Sutures

Variable	Lubrocoat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	131	0.69	(0.85)	0 to 4	134	0.96	(1.00)	0 to 5	0.023
Total Possible	131	2.28	(0.91)	1 to 6	134	2.23	(0.94)	1 to 6	0.654
Proportion	131	0.282	(0.327)	0.00 to 1.00	134	0.381	(0.367)	0.00 to 1.00	0.022
Severity Score	131	0.59	(0.83)	0.0 to 3.0	134	0.90	(1.01)	0.0 to 3.0	0.007
Extent Score	131	0.44	(0.62)	0.0 to 3.0	134	0.70	(0.85)	0.0 to 3.0	0.005
Modified AFS Score(0-16)	131	1.41	(2.52)	0.0 to 16.0	134	2.78	(4.19)	0.0 to 16.0	0.001
Surgical site Adhesions	131	1.01	(1.00)	0 to 4	134	1.28	(1.19)	0 to 5	0.042
Total Possible	131	2.69	(0.88)	1 to 6	134	2.62	(1.07)	1 to 6	0.533
Proportion	131	0.354	(0.322)	0.00 to 1.00	134	0.441	(0.350)	0.00 to 1.00	0.036
Severity Score(0-3)	131	0.73	(0.82)	0.0 to 3.0	134	1.02	(0.97)	0.0 to 3.0	0.010
Extent Score(0-3)	131	0.60	(0.68)	0.0 to 3.0	134	0.83	(0.84)	0.0 to 3.0	0.015
Modified AFS Score(0-16)	131	1.96	(2.87)	0.0 to 16.0	134	3.27	(4.29)	0.0 to 16.0	0.004
Surgical site DeNovo Adhesions	131	0.69	(0.85)	0 to 4	134	0.96	(1.00)	0 to 5	0.023
Total Possible	131	2.28	(0.91)	1 to 6	134	2.23	(0.94)	1 to 6	0.654
Proportion	131	0.282	(0.327)	0.00 to 1.00	134	0.381	(0.367)	0.00 to 1.00	0.022
Severity Score(0-3)	131	0.59	(0.83)	0.0 to 3.0	134	0.90	(1.01)	0.0 to 3.0	0.007
Extent Score(0-3)	131	0.44	(0.62)	0.0 to 3.0	134	0.70	(0.85)	0.0 to 3.0	0.005
Modified AFS Score(0-16)	131	1.41	(2.52)	0.0 to 16.0	134	2.78	(4.19)	0.0 to 16.0	0.001
Non-surgical site DeNovo Adhesions	0	.	.	.	0	.	.	.	.
Total Possible	0	.	.	.	0	.	.	.	.
Proportion	0	.	.	.	0	.	.	.	.
Severity Score(0-3)	0	.	.	.	0	.	.	.	.
Extent Score(0-3)	0	.	.	.	0	.	.	.	.
Modified AFS Score(0-16)	0	.	.	.	0	.	.	.	.
Reformed Adhesions	33	1.24	(0.87)	0 to 3	30	1.47	(0.94)	0 to 4	0.328
Total Possible	33	1.64	(0.86)	1 to 4	30	1.73	(0.94)	1 to 4	0.671
Proportion	33	0.765	(0.377)	0.00 to 1.00	30	0.872	(0.289)	0.00 to 1.00	0.214
Severity Score(0-3)	33	1.67	(1.17)	0.0 to 3.0	30	1.89	(1.02)	0.0 to 3.0	0.432
Extent Score(0-3)	33	1.56	(1.09)	0.0 to 3.0	30	1.84	(0.98)	0.0 to 3.0	0.292
Modified AFS Score(0-16)	33	5.61	(5.81)	0.0 to 16.0	30	6.69	(5.81)	0.0 to 16.0	0.464

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LIFECORE, INC.  
 Lubricoat Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 5.1.17.1: Adhesion Data -Sites Lysed Using Sharp Dissection

Variable	Lubricoat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	34	4.59	(3.16)	1 to 13	35	4.83	(2.72)	1 to 11	0.736
Total Possible	34	4.59	(3.16)	1 to 13	35	4.83	(2.72)	1 to 11	0.736
Proportion	34	1.000	(0.000)	1.00 to 1.00	35	1.000	(0.000)	1.00 to 1.00	.
Severity Score(0-3)	34	2.34	(0.83)	1.0 to 3.0	35	2.10	(0.87)	1.0 to 3.0	0.259
Extent Score(0-3)	34	1.90	(0.62)	1.0 to 3.0	35	1.79	(0.49)	1.0 to 3.0	0.434
Modified AFS Score(0-16)	34	6.89	(4.54)	1.0 to 16.0	35	5.89	(4.19)	1.0 to 16.0	0.347
Adhesions Lysed	34	4.59	(3.16)	1 to 13	35	4.83	(2.72)	1 to 11	0.736
Surgical Sites	34	4.74	(3.37)	1 to 14	35	4.89	(2.69)	1 to 11	0.838
Mild Adhesions	34	1.38	(1.86)	0 to 6	35	2.17	(2.80)	0 to 11	0.174
Severe Adhesions	34	3.21	(3.08)	0 to 12	35	2.66	(2.59)	0 to 9	0.426
Localized Adhesions	34	1.50	(2.12)	0 to 10	35	1.83	(1.93)	0 to 9	0.503
Moderate Adhesions	34	1.85	(1.99)	0 to 7	35	2.17	(2.31)	0 to 9	0.542
Extensive Adhesions	34	1.24	(2.12)	0 to 7	35	0.83	(1.42)	0 to 6	0.351
<b>Second Look</b>									
Adhesions	34	2.82	(2.37)	0 to 11	35	3.74	(2.41)	0 to 9	0.114
Total Possible	34	4.74	(3.37)	1 to 14	35	4.89	(2.69)	1 to 11	0.838
Proportion	34	0.613	(0.350)	0.00 to 1.00	35	0.752	(0.310)	0.00 to 1.00	0.087
Severity Score(0-3)	34	1.29	(0.94)	0.0 to 3.0	35	1.79	(1.07)	0.0 to 3.0	0.046
Extent Score(0-3)	34	1.14	(0.85)	0.0 to 3.0	35	1.61	(0.83)	0.0 to 3.0	0.025
Modified AFS Score(0-16)	34	4.03	(4.25)	0.0 to 16.0	35	6.21	(5.01)	0.0 to 16.0	0.056

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

**TABLE 5.1.17.2: DeNovo, Surgical Site and Reformed Adhesions -Sites Lysed Using Sharp Dissection**

Variable	Lubricote Gel			Lactated Ringer's Solution			P		
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	5	0.60	(0.55)	0 to 1	2	0.00	(0.00)	0 to 0	0.203
Total Possible	5	1.00	(0.00)	1 to 1	2	1.00	(0.00)	1 to 1	.
Proportion	5	0.600	(0.548)	0.00 to 1.00	2	0.000	(0.000)	0.00 to 0.00	0.203
Severity Score	5	1.40	(1.52)	0.0 to 3.0	2	0.00	(0.00)	0.0 to 0.0	0.272
Extent Score	5	1.00	(1.00)	0.0 to 2.0	2	0.00	(0.00)	0.0 to 0.0	0.239
Modified AFS Score(0-16)	5	3.40	(4.22)	0.0 to 8.0	2	0.00	(0.00)	0.0 to 0.0	0.331
Surgical site Adhesions	34	2.82	(2.37)	0 to 11	35	3.74	(2.41)	0 to 9	0.114
Total Possible	34	4.74	(3.37)	1 to 14	35	4.89	(2.69)	1 to 11	0.838
Proportion	34	0.613	(0.350)	0.00 to 1.00	35	0.752	(0.310)	0.00 to 1.00	0.087
Severity Score(0-3)	34	1.29	(0.94)	0.0 to 3.0	35	1.79	(1.07)	0.0 to 3.0	0.046
Extent Score(0-3)	34	1.14	(0.85)	0.0 to 3.0	35	1.61	(0.83)	0.0 to 3.0	0.025
Modified AFS Score(0-16)	34	4.03	(4.25)	0.0 to 16.0	35	6.21	(5.01)	0.0 to 16.0	0.056
Surgical site DeNovo Adhesions	5	0.60	(0.55)	0 to 1	2	0.00	(0.00)	0 to 0	0.203
Total Possible	5	1.00	(0.00)	1 to 1	2	1.00	(0.00)	1 to 1	.
Proportion	5	0.600	(0.548)	0.00 to 1.00	2	0.000	(0.000)	0.00 to 0.00	0.203
Severity Score(0-3)	5	1.40	(1.52)	0.0 to 3.0	2	0.00	(0.00)	0.0 to 0.0	0.239
Extent Score(0-3)	5	1.00	(1.00)	0.0 to 2.0	2	0.00	(0.00)	0.0 to 0.0	0.331
Modified AFS Score(0-16)	5	3.40	(4.22)	0.0 to 8.0	2	0.00	(0.00)	0.0 to 0.0	.
Non-surgical site DeNovo Adhesions	0	.	.	. to .	0	.	.	. to .	.
Total Possible	0	.	.	. to .	0	.	.	. to .	.
Proportion	0	.	.	. to .	0	.	.	. to .	.
Severity Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Extent Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Modified AFS Score(0-16)	0	.	.	. to .	0	.	.	. to .	.
Reformed Adhesions	34	2.74	(2.34)	0 to 11	35	3.74	(2.41)	0 to 9	0.082
Total Possible	34	4.59	(3.16)	1 to 13	35	4.83	(2.72)	1 to 11	0.736
Proportion	34	0.609	(0.355)	0.00 to 1.00	35	0.764	(0.310)	0.00 to 1.00	0.058
Severity Score(0-3)	34	1.28	(0.96)	0.0 to 3.0	35	1.82	(1.08)	0.0 to 3.0	0.032
Extent Score(0-3)	34	1.14	(0.86)	0.0 to 3.0	35	1.63	(0.82)	0.0 to 3.0	0.019
Modified AFS Score(0-16)	34	4.03	(4.29)	0.0 to 16.0	35	6.28	(4.98)	0.0 to 16.0	0.048

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.18.1: Adhesion Data -Sites Lysed Using Cautery

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	39	5.85	(3.33)	1 to 13	37	6.35	(4.12)	1 to 14	0.558
Total Possible	39	5.87	(3.33)	1 to 13	37	6.35	(4.12)	1 to 14	0.578
Proportion	39	0.996	(0.023)	0.86 to 1.00	37	1.000	(0.000)	1.00 to 1.00	0.333
Severity Score(0-3)	39	2.47	(0.64)	1.0 to 3.0	37	2.09	(0.73)	1.0 to 3.0	0.019
Extent Score(0-3)	39	1.67	(0.55)	1.0 to 2.7	37	1.77	(0.48)	1.0 to 3.0	0.380
Modified AFS Score(0-16)	39	6.15	(3.10)	1.0 to 12.4	37	5.80	(3.66)	1.0 to 16.0	0.652
Adhesions Lysed	39	5.87	(3.33)	1 to 13	37	6.35	(4.12)	1 to 14	0.578
Surgical Sites	39	5.87	(3.33)	1 to 13	37	6.35	(4.12)	1 to 14	0.578
Mild Adhesions	39	1.62	(1.97)	0 to 7	37	2.54	(2.21)	0 to 9	0.057
Severe Adhesions	39	4.23	(3.01)	0 to 11	37	3.81	(3.26)	0 to 10	0.562
Localized Adhesions	39	2.56	(2.41)	0 to 9	37	2.38	(2.13)	0 to 9	0.724
Moderate Adhesions	39	2.13	(2.23)	0 to 9	37	2.57	(2.43)	0 to 8	0.414
Extensive Adhesions	39	1.15	(2.10)	0 to 8	37	1.41	(2.29)	0 to 9	0.619
<b>Second Look</b>									
Adhesions	39	2.49	(2.44)	0 to 8	37	4.03	(3.21)	0 to 12	0.021
Total Possible	39	5.87	(3.33)	1 to 13	37	6.35	(4.12)	1 to 14	0.578
Proportion	39	0.414	(0.344)	0.00 to 1.00	37	0.689	(0.331)	0.00 to 1.00	0.001
Severity Score(0-3)	39	0.89	(0.87)	0.0 to 3.0	37	1.47	(0.96)	0.0 to 3.0	0.007
Extent Score(0-3)	39	0.67	(0.67)	0.0 to 2.3	37	1.26	(0.77)	0.0 to 3.0	0.001
Modified AFS Score(0-16)	39	2.33	(2.92)	0.0 to 10.0	37	4.21	(4.00)	0.0 to 16.0	0.022

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.18.2: DeNovo, Surgical Site and Reformed Adhesions -Sites Lysed Using Cautery

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	1	0.00	.	0 to 0	0	.	.	. to .	.
Total Possible	1	1.00	.	1 to 1	0	.	.	. to .	.
Proportion	1	0.000	.	0.00 to 0.00	0	.	.	. to .	.
Severity Score	1	0.00	.	0.0 to 0.0	0	.	.	. to .	.
Extent Score	1	0.00	.	0.0 to 0.0	0	.	.	. to .	.
Modified AFS Score(0-16)	1	0.00	.	0.0 to 0.0	0	.	.	. to .	.
Surgical site Adhesions	39	2.49 (2.44)	.	0 to 8	37	4.03 (3.21)	.	0 to 12	0.021
Total Possible	39	5.87 (3.33)	.	1 to 13	37	6.35 (4.12)	.	1 to 14	0.578
Proportion	39	0.414 (0.344)	.	0.00 to 1.00	37	0.689 (0.331)	.	0.00 to 1.00	0.001
Severity Score(0-3)	39	0.89 (0.87)	.	0.0 to 3.0	37	1.47 (0.96)	.	0.0 to 3.0	0.007
Extent Score(0-3)	39	0.67 (0.67)	.	0.0 to 2.3	37	1.26 (0.77)	.	0.0 to 3.0	0.001
Modified AFS Score(0-16)	39	2.33 (2.92)	.	0.0 to 10.0	37	4.21 (4.00)	.	0.0 to 16.0	0.022
Surgical site DeNovo Adhesions	1	0.00	.	0 to 0	0	.	.	. to .	.
Total Possible	1	1.00	.	1 to 1	0	.	.	. to .	.
Proportion	1	0.000	.	0.00 to 0.00	0	.	.	. to .	.
Severity Score(0-3)	1	0.00	.	0.0 to 0.0	0	.	.	. to .	.
Extent Score(0-3)	1	0.00	.	0.0 to 0.0	0	.	.	. to .	.
Modified AFS Score(0-16)	1	0.00	.	0.0 to 0.0	0	.	.	. to .	.
Non-surgical site DeNovo Adhesions	0	.	.	. to .	0	.	.	. to .	.
Total Possible	0	.	.	. to .	0	.	.	. to .	.
Proportion	0	.	.	. to .	0	.	.	. to .	.
Severity Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Extent Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Modified AFS Score(0-16)	0	.	.	. to .	0	.	.	. to .	.
Reformed Adhesions	39	2.49 (2.44)	.	0 to 8	37	4.03 (3.21)	.	0 to 12	0.021
Total Possible	39	5.85 (3.33)	.	1 to 13	37	6.35 (4.12)	.	1 to 14	0.558
Proportion	39	0.415 (0.344)	.	0.00 to 1.00	37	0.689 (0.331)	.	0.00 to 1.00	0.001
Severity Score(0-3)	39	0.90 (0.87)	.	0.0 to 3.0	37	1.47 (0.96)	.	0.0 to 3.0	0.008
Extent Score(0-3)	39	0.67 (0.67)	.	0.0 to 2.3	37	1.26 (0.77)	.	0.0 to 3.0	0.001
Modified AFS Score(0-16)	39	2.34 (2.92)	.	0.0 to 10.0	37	4.21 (4.00)	.	0.0 to 16.0	0.022

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LIFECORE, INC.  
Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
Protocol PTL-0013 and PTL-0022

TABLE 5.1.19.1: Adhesion Data -Sites Lysed Using Laser

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
<b>Baseline</b>									
Adhesions	3	3.33	(2.08)	1 to 5	3	2.67	(1.15)	2 to 4	0.653
Total Possible	3	3.33	(2.08)	1 to 5	3	2.67	(1.15)	2 to 4	0.653
Proportion	3	1.000	(0.000)	1.00 to 1.00	3	1.000	(0.000)	1.00 to 1.00	.
Severity Score(0-3)	3	2.23	(0.75)	1.5 to 3.0	3	1.00	(0.00)	1.0 to 1.0	0.047
Extent Score(0-3)	3	2.08	(1.01)	1.0 to 3.0	3	1.67	(0.58)	1.0 to 2.0	0.569
Modified AFS Score(0-16)	3	8.10	(6.97)	2.8 to 16.0	3	1.67	(0.58)	1.0 to 2.0	0.187
Adhesions Lysed	3	3.33	(2.08)	1 to 5	3	2.67	(1.15)	2 to 4	0.653
Surgical Sites	3	3.33	(2.08)	1 to 5	3	2.67	(1.15)	2 to 4	0.653
Mild Adhesions	3	1.67	(1.53)	0 to 3	3	2.67	(1.15)	2 to 4	0.417
Severe Adhesions	3	1.67	(1.15)	1 to 3	3	0.00	(0.00)	0 to 0	0.067
Localized Adhesions	3	1.67	(2.89)	0 to 5	3	0.67	(1.15)	0 to 2	0.607
Moderate Adhesions	3	1.00	(1.73)	0 to 3	3	2.00	(2.00)	0 to 4	0.548
Extensive Adhesions	3	0.67	(0.58)	0 to 1	3	0.00	(0.00)	0 to 0	0.116
<b>Second Look</b>									
Adhesions	3	2.00	(1.00)	1 to 3	3	0.67	(0.58)	0 to 1	0.116
Total Possible	3	3.33	(2.08)	1 to 5	3	2.67	(1.15)	2 to 4	0.653
Proportion	3	0.700	(0.265)	0.50 to 1.00	3	0.250	(0.250)	0.00 to 0.50	0.099
Severity Score(0-3)	3	1.37	(1.42)	0.5 to 3.0	3	0.25	(0.25)	0.0 to 0.5	0.250
Extent Score(0-3)	3	0.90	(0.36)	0.5 to 1.2	3	0.25	(0.25)	0.0 to 0.5	0.062
Modified AFS Score(0-16)	3	1.90	(1.85)	0.5 to 4.0	3	0.25	(0.25)	0.0 to 0.5	0.201

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LIFECORE, INC.  
Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
Protocol PTL-0013 and PTL-0022

TABLE 5.1.19.2: DeNovo, Surgical Site and Reformed Adhesions -Sites Lysed Using Laser

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	0	.	.	. to .	0	.	.	. to .	.
Total Possible	0	.	.	. to .	0	.	.	. to .	.
Proportion	0	.	.	. to .	0	.	.	. to .	.
Severity Score	0	.	.	. to .	0	.	.	. to .	.
Extent Score	0	.	.	. to .	0	.	.	. to .	.
Modified AFS Score(0-16)	0	.	.	. to .	0	.	.	. to .	.
Surgical site Adhesions	3	2.00	(1.00)	1 to 3	3	0.67	(0.58)	0 to 1	0.116
Total Possible	3	3.33	(2.08)	1 to 5	3	2.67	(1.15)	2 to 4	0.653
Proportion	3	0.700	(0.265)	0.50 to 1.00	3	0.250	(0.250)	0.00 to 0.50	0.099
Severity Score(0-3)	3	1.37	(1.42)	0.5 to 3.0	3	0.25	(0.25)	0.0 to 0.5	0.250
Extent Score(0-3)	3	0.90	(0.36)	0.5 to 1.2	3	0.25	(0.25)	0.0 to 0.5	0.062
Modified AFS Score(0-16)	3	1.90	(1.85)	0.5 to 4.0	3	0.25	(0.25)	0.0 to 0.5	0.201
Surgical site DeNovo Adhesions	0	.	.	. to .	0	.	.	. to .	.
Total Possible	0	.	.	. to .	0	.	.	. to .	.
Proportion	0	.	.	. to .	0	.	.	. to .	.
Severity Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Extent Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Modified AFS Score(0-16)	0	.	.	. to .	0	.	.	. to .	.
Non-surgical site DeNovo Adhesions	0	.	.	. to .	0	.	.	. to .	.
Total Possible	0	.	.	. to .	0	.	.	. to .	.
Proportion	0	.	.	. to .	0	.	.	. to .	.
Severity Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Extent Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Modified AFS Score(0-16)	0	.	.	. to .	0	.	.	. to .	.
Reformed Adhesions	3	2.00	(1.00)	1 to 3	3	0.67	(0.58)	0 to 1	0.116
Total Possible	3	3.33	(2.08)	1 to 5	3	2.67	(1.15)	2 to 4	0.653
Proportion	3	0.700	(0.265)	0.50 to 1.00	3	0.250	(0.250)	0.00 to 0.50	0.099
Severity Score(0-3)	3	1.37	(1.42)	0.5 to 3.0	3	0.25	(0.25)	0.0 to 0.5	0.250
Extent Score(0-3)	3	0.90	(0.36)	0.5 to 1.2	3	0.25	(0.25)	0.0 to 0.5	0.062
Modified AFS Score(0-16)	3	1.90	(1.85)	0.5 to 4.0	3	0.25	(0.25)	0.0 to 0.5	0.201

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**LIFECORE, INC.**  
**Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions**  
**Protocol PTL-0013 and PTL-0022**

TABLE 5.1.20.1: Adhesion Data -Sites Lysed Using Blunt Dissection

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Baseline									
Adhesions	29	3.69	(2.44)	1 to 10	20	3.25	(1.89)	1 to 8	0.501
Total Possible	29	3.69	(2.44)	1 to 10	20	3.25	(1.89)	1 to 8	0.501
Proportion	29	1.000	(0.000)	1.00 to 1.00	20	1.000	(0.000)	1.00 to 1.00	0.000
Severity Score(0-3)	29	2.00	(0.91)	1.0 to 3.0	20	2.51	(0.83)	1.0 to 3.0	0.052
Extent Score(0-3)	29	1.88	(0.59)	1.0 to 3.0	20	2.16	(0.74)	1.0 to 3.0	0.154
Modified AFS Score(0-16)	29	5.62	(4.29)	1.0 to 16.0	20	9.41	(5.80)	1.0 to 16.0	0.011
Adhesions Lysed	29	3.69	(2.44)	1 to 10	20	3.25	(1.89)	1 to 8	0.501
Surgical Sites	29	3.69	(2.44)	1 to 10	20	3.25	(1.89)	1 to 8	0.501
Mild Adhesions	29	1.52	(1.72)	0 to 6	20	0.90	(1.94)	0 to 8	0.248
Severe Adhesions	29	2.17	(2.55)	0 to 8	20	2.35	(1.93)	0 to 8	0.793
Localized Adhesions	29	1.31	(1.65)	0 to 6	20	0.95	(1.64)	0 to 7	0.455
Moderate Adhesions	29	1.41	(1.68)	0 to 6	20	1.10	(1.86)	0 to 8	0.542
Extensive Adhesions	29	0.97	(1.55)	0 to 7	20	1.20	(1.36)	0 to 4	0.587
Second Look									
Adhesions	29	2.45	(1.94)	0 to 8	20	2.90	(1.68)	0 to 8	0.402
Total Possible	29	3.69	(2.44)	1 to 10	20	3.25	(1.89)	1 to 8	0.501
Proportion	29	0.628	(0.392)	0.00 to 1.00	20	0.908	(0.251)	0.00 to 1.00	0.007
Severity Score(0-3)	29	1.28	(1.01)	0.0 to 3.0	20	2.30	(0.92)	0.0 to 3.0	0.001
Extent Score(0-3)	29	1.19	(0.88)	0.0 to 2.7	20	1.84	(0.90)	0.0 to 3.0	0.016
Modified AFS Score(0-16)	29	3.68	(3.56)	0.0 to 12.0	20	7.99	(5.49)	0.0 to 16.0	0.002

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TABLE 5.1.20.2: DeNovo, Surgical Site and Reformed Adhesions -Sites Lysed Using Blunt Dissection

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
DeNovo Adhesions	0	.	.	. to .	0	.	.	. to .	.
Total Possible	0	.	.	. to .	0	.	.	. to .	.
Proportion	0	.	.	. to .	0	.	.	. to .	.
Severity Score	0	.	.	. to .	0	.	.	. to .	.
Extent Score	0	.	.	. to .	0	.	.	. to .	.
Modified AFS Score(0-16)	0	.	.	. to .	0	.	.	. to .	.
Surgical site Adhesions	29	2.45 (1.94)	0 to 8	20	2.90 (1.68)	0 to 8	0.402		
Total Possible	29	3.69 (2.44)	1 to 10	20	3.25 (1.89)	1 to 8	0.501		
Proportion	29	0.628 (0.392)	0.00 to 1.00	20	0.908 (0.251)	0.00 to 1.00	0.007		
Severity Score(0-3)	29	1.28 (1.01)	0.0 to 3.0	20	2.30 (0.92)	0.0 to 3.0	0.001		
Extent Score(0-3)	29	1.19 (0.88)	0.0 to 2.7	20	1.84 (0.90)	0.0 to 3.0	0.016		
Modified AFS Score(0-16)	29	3.68 (3.56)	0.0 to 12.0	20	7.99 (5.49)	0.0 to 16.0	0.002		
Surgical site DeNovo Adhesions	0	.	.	. to .	0	.	.	. to .	.
Total Possible	0	.	.	. to .	0	.	.	. to .	.
Proportion	0	.	.	. to .	0	.	.	. to .	.
Severity Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Extent Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Modified AFS Score(0-16)	0	.	.	. to .	0	.	.	. to .	.
Non-surgical site DeNovo Adhesions	0	.	.	. to .	0	.	.	. to .	.
Total Possible	0	.	.	. to .	0	.	.	. to .	.
Proportion	0	.	.	. to .	0	.	.	. to .	.
Severity Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Extent Score(0-3)	0	.	.	. to .	0	.	.	. to .	.
Modified AFS Score(0-16)	0	.	.	. to .	0	.	.	. to .	.
Reformed Adhesions	29	2.45 (1.94)	0 to 8	20	2.90 (1.68)	0 to 8	0.402		
Total Possible	29	3.69 (2.44)	1 to 10	20	3.25 (1.89)	1 to 8	0.501		
Proportion	29	0.628 (0.392)	0.00 to 1.00	20	0.908 (0.251)	0.00 to 1.00	0.007		
Severity Score(0-3)	29	1.28 (1.01)	0.0 to 3.0	20	2.30 (0.92)	0.0 to 3.0	0.001		
Extent Score(0-3)	29	1.19 (0.88)	0.0 to 2.7	20	1.84 (0.90)	0.0 to 3.0	0.016		
Modified AFS Score(0-16)	29	3.68 (3.56)	0.0 to 12.0	20	7.99 (5.49)	0.0 to 16.0	0.002		

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TABLE 5.2.1: Baseline Modified AFS Score by Site

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Caudal Anterior Peritoneum	131	0.47	(1.96)	0 to 16	134	0.22	(1.58)	0 to 16	0.270
R Cefalid Anterior Peritoneum	131	0.35	(1.50)	0 to 8	134	0.33	(1.75)	0 to 16	0.910
L Cefalid Anterior Peritoneum	131	0.25	(1.19)	0 to 8	134	0.10	(0.78)	0 to 8	0.233
Anterior Peritoneum Incision	0	.	.	0 to .	0	.	.	0 to .	.
Small Bowel	131	0.31	(1.41)	0 to 8	134	0.39	(1.67)	0 to 8	0.664
Anterior Uterus	131	1.03	(3.34)	0 to 16	134	0.31	(1.66)	0 to 16	0.027
Posterior Uterus	131	1.26	(2.84)	0 to 16	134	1.56	(3.63)	0 to 16	0.455
Omentum	131	1.01	(2.56)	0 to 8	134	0.72	(2.13)	0 to 8	0.314
R Large Bowel	131	0.41	(1.70)	0 to 8	134	0.33	(1.54)	0 to 8	0.673
L Large Bowel	131	0.44	(1.81)	0 to 8	134	0.18	(1.02)	0 to 8	0.145
Rectosigmoid Portion	131	1.00	(3.13)	0 to 16	134	1.15	(3.26)	0 to 16	0.704
Cul-de-sac	131	0.90	(2.97)	0 to 16	134	1.13	(3.53)	0 to 16	0.573
R Pelvic Sidewall	131	0.52	(1.82)	0 to 16	134	0.77	(2.81)	0 to 16	0.393
L Pelvic Sidewall	131	0.98	(3.08)	0 to 16	134	0.43	(1.41)	0 to 8	0.061
R Lateral Ovary	128	1.57	(3.80)	0 to 16	130	1.63	(4.11)	0 to 16	0.903
R Medial Ovary	128	0.91	(2.86)	0 to 16	130	1.35	(3.95)	0 to 16	0.308
R Ovarian Fossa	128	1.31	(3.78)	0 to 16	132	1.59	(4.29)	0 to 16	0.580
L Lateral Ovary	129	2.33	(4.85)	0 to 16	129	2.63	(5.40)	0 to 16	0.637
L Medial Ovary	129	1.82	(4.49)	0 to 16	129	1.85	(4.67)	0 to 16	0.957
L Ovarian Fossa	130	1.73	(4.46)	0 to 16	131	2.12	(5.17)	0 to 16	0.513
R Tube	128	1.02	(2.97)	0 to 16	128	1.08	(3.38)	0 to 16	0.875
R Ampulla	128	1.51	(4.06)	0 to 16	128	1.24	(3.31)	0 to 16	0.567
L Tube	129	1.69	(3.95)	0 to 16	128	1.54	(4.02)	0 to 16	0.762
L Ampulla	130	1.82	(4.43)	0 to 16	129	1.45	(3.79)	0 to 16	0.467

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TABLE 5.2.2: Second Look Modified AFS Score by Site

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Caudal Anterior Peritoneum	128	0.66	(2.03)	0 to 16	130	1.55	(4.24)	0 to 16	0.034
R Cefalid Anterior Peritoneum	129	0.25	(1.00)	0 to 8	131	1.16	(3.26)	0 to 16	0.003
L Cefalid Anterior Peritoneum	129	0.20	(0.79)	0 to 4	133	1.49	(4.15)	0 to 16	0.001
Anterior Peritoneum Incision	131	0.83	(2.83)	0 to 16	133	2.10	(4.91)	0 to 16	0.011
Small Bowel	129	0.82	(2.26)	0 to 8	133	1.68	(3.10)	0 to 8	0.011
Anterior Uterus	127	0.98	(2.57)	0 to 16	128	1.80	(4.13)	0 to 16	0.058
Posterior Uterus	125	2.62	(4.67)	0 to 16	127	3.95	(5.47)	0 to 16	0.038
Omentum	128	1.34	(2.77)	0 to 8	133	2.54	(3.58)	0 to 8	0.003
R Large Bowel	128	0.84	(2.27)	0 to 8	131	0.98	(2.56)	0 to 8	0.658
L Large Bowel	130	0.78	(1.89)	0 to 8	132	1.79	(3.15)	0 to 8	0.002
Rectosigmoid Portion	126	1.78	(2.93)	0 to 16	125	1.33	(3.95)	0 to 16	0.284
Cul-de-sac	125	0.89	(2.31)	0 to 16	133	1.42	(3.84)	0 to 16	0.013
R Pelvic Sidewall	129	0.53	(1.32)	0 to 8	129	2.36	(4.81)	0 to 16	0.053
L Pelvic Sidewall	127	1.38	(3.13)	0 to 16	128	2.45	(4.74)	0 to 16	0.117
R Lateral Ovary	124	1.60	(3.66)	0 to 16	128	2.17	(4.48)	0 to 16	0.237
R Medial Ovary	125	1.56	(3.69)	0 to 16	127	2.17	(4.48)	0 to 16	0.049
R Ovarian Fossa	126	1.11	(3.12)	0 to 16	130	2.12	(4.81)	0 to 16	0.074
L Lateral Ovary	124	2.23	(4.36)	0 to 16	122	3.37	(5.56)	0 to 16	0.124
L Medial Ovary	128	2.59	(5.06)	0 to 16	126	3.65	(5.91)	0 to 16	0.001
L Ovarian Fossa	125	1.31	(3.81)	0 to 16	126	3.57	(6.37)	0 to 16	0.022
R Tube	127	1.22	(2.99)	0 to 16	126	2.33	(4.55)	0 to 16	0.023
R Ampulla	125	1.01	(2.87)	0 to 16	126	2.10	(4.51)	0 to 16	0.051
L Tube	125	1.98	(4.33)	0 to 16	123	3.18	(5.28)	0 to 16	0.117
L Ampulla	125	1.82	(4.27)	0 to 16	126	2.76	(5.20)	0 to 16	

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LIFECORE, INC.  
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TABLE 5.3.1: Baseline Proportion of Adhesions by Site

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
Caudal Anterior Peritoneum	10	131	7.6%	5	134	3.7%	0.193
R Cefalid Anterior Peritoneum	8	131	6.1%	8	134	6.0%	1.000
L Cefalid Anterior Peritoneum	7	131	5.3%	4	134	3.0%	0.373
Anterior Peritoneum Incision	. / 0	. / .	. %	. / 0	. / .	. %	0.373
Small Bowel	8	131	6.1%	8	134	6.0%	1.000
Anterior Uterus	18	131	13.7%	9	134	6.7%	0.069
Posterior Uterus	29	131	22.1%	34	134	25.4%	0.566
Omentum	21	131	16.0%	18	134	13.4%	0.605
R Large Bowel	9	131	6.9%	7	134	5.2%	0.615
L Large Bowel	8	131	6.1%	6	134	4.5%	0.594
Rectosigmoid Portion	20	131	15.3%	24	134	17.9%	0.622
Cul-de-sac	18	131	13.7%	22	134	16.4%	0.608
R Pelvic Sidewall	19	131	14.5%	16	134	11.9%	0.589
L Pelvic Sidewall	21	131	16.0%	20	134	14.9%	0.866
R Lateral Ovary	33	128	25.8%	31	130	23.8%	0.774
R Medial Ovary	21	128	16.4%	27	130	20.8%	0.425
R Ovarian Fossa	19	128	14.8%	21	132	15.9%	0.864
L Lateral Ovary	37	129	28.7%	35	129	27.1%	0.890
L Medial Ovary	27	129	20.9%	34	129	26.4%	0.379
L Ovarian Fossa	26	130	20.0%	27	131	20.6%	1.000
R Tube	25	128	19.5%	24	128	18.8%	1.000
R Ampulla	26	128	20.3%	28	128	21.9%	0.878
L Tube	35	129	27.1%	26	128	20.3%	0.241
L Ampulla	33	130	25.4%	30	129	23.3%	0.772

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TABLE 5.3.2: Second Look Proportion of Adhesions by Site

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
Caudal Anterior Peritoneum	26	128	20.3%	27	130	20.8%	1.000
R Cefalid Anterior Peritoneum	13	129	10.1%	23	131	17.6%	0.106
L Cefalid Anterior Peritoneum	11	129	8.5%	25	133	18.8%	0.019
Anterior Peritoneum Incision	16	131	12.2%	29	134	21.6%	0.050
Small Bowel	20	129	15.5%	37	133	27.8%	0.017
Anterior Uterus	35	127	27.6%	44	128	34.4%	0.279
Posterior Uterus	63	125	50.4%	79	127	62.2%	0.075
Omentum	32	128	25.0%	52	133	39.1%	0.017
R Large Bowel	21	128	16.4%	19	131	14.5%	0.732
L Large Bowel	30	130	23.1%	40	132	30.3%	0.210
Rectosigmoid Portion	61	126	48.4%	64	129	49.6%	0.901
Cul-de-sac	31	125	24.8%	26	125	20.8%	0.547
R Pelvic Sidewall	32	129	24.8%	32	133	24.1%	1.000
L Pelvic Sidewall	46	127	36.2%	49	129	38.0%	0.797
R Lateral Ovary	46	124	37.1%	50	128	39.1%	0.796
R Medial Ovary	42	125	33.6%	45	127	35.4%	0.792
R Ovarian Fossa	31	126	24.6%	33	130	25.4%	1.000
L Lateral Ovary	51	124	41.1%	58	122	47.5%	0.369
L Medial Ovary	50	128	39.1%	56	126	44.4%	0.445
L Ovarian Fossa	29	125	23.2%	41	126	32.5%	0.122
R Tube	35	127	27.6%	52	126	41.3%	0.025
R Ampulla	33	125	26.4%	45	126	35.7%	0.134
L Tube	43	125	34.4%	60	123	48.8%	0.028
L Ampulla	39	125	31.2%	49	126	38.9%	0.234

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TABLE 5.4.1: Modified AFS Score by Center -All Patients

		Lubricote Gel				Lactated Ringer's Solution			
		N	Pre	Post	LS Mean	N	Pre	Post	LS Mean
<b>All Patients</b>		131	1.07	1.28	.	134	1.07	2.33	.
US	Center 02	21	0.89	1.39	1.48	18	0.61	2.85	3.08
	Center 03	6	0.09	1.49	1.98	5	1.77	4.66	4.31
	Centers 04 and 12	8	0.11	0.83	1.31	11	0.33	1.08	1.45
	Center 06	6	2.32	1.86	1.24	8	0.63	1.73	1.95
	Center 07	5	0.92	1.47	1.55	6	0.17	2.17	2.62
	Center 08	6	0.20	1.12	1.55	7	0.00	1.32	1.86
	Center 09	12	0.77	0.86	1.01	10	0.21	2.71	3.14
	Center 10	14	0.02	2.22	2.75	13	0.45	2.41	2.71
	Center 11	15	1.88	1.48	1.07	17	1.64	3.24	2.96
Europe	Center 21	12	0.99	0.77	0.82	14	1.96	2.28	1.84
	Center 23	10	1.81	0.97	0.61	9	1.11	1.40	1.38
	Center 25	5	1.31	0.52	0.40	8	3.03	2.20	1.22
	Centers 27 and 29	11	2.42	1.18	0.51	8	2.07	1.74	1.24

**ANALYSIS OF VARIANCE (Including Baseline Interaction Term)**

Source: Treatment	p = 0.0055
Source: Center	p = 0.0340
Source: Treatment*Center	p = 0.8114
Source: Baseline Level	p = 0.0000
Source: Treatment*Baseline	p = 0.5839

**ANALYSIS OF VARIANCE (Final)**

Source: Treatment	p = 0.0002
Source: Center	p = 0.0322
Source: Treatment*Center	p = 0.7873
Source: Pre-treatment Level	p = 0.0000

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TABLE 5.4.2: Modified AFS Score by Center -American Patients

		Lubricote Gel				Lactated Ringer's Solution			
		N	Pre	Post	LS Mean	N	Pre	Post	LS Mean
All Patients		93	0.83	1.44	.	95	0.69	2.48	.
US	Center 02	21	0.89	1.39	1.30	18	0.61	2.85	2.95
	Center 03	6	0.09	1.49	1.96	5	1.77	4.66	3.95
	Centers 04 and 12	8	0.11	0.83	1.29	11	0.33	1.08	1.38
	Center 06	6	2.32	1.86	0.76	8	0.63	1.73	1.82
	Center 07	5	0.92	1.47	1.36	6	0.17	2.17	2.59
	Center 08	6	0.20	1.12	1.51	7	0.00	1.32	1.86
	Center 09	12	0.77	0.86	0.85	10	0.21	2.71	3.10
	Center 10	14	0.02	2.22	2.75	13	0.45	2.41	2.62
	Center 11	15	1.88	1.48	0.69	17	1.64	3.24	2.62

**ANALYSIS OF VARIANCE (Including Baseline Interaction Term)**

Source: Treatment	p = 0.0145
Source: Center	p = 0.4474
Source: Treatment*Center	p = 0.6763
Source: Baseline Level	p = 0.0000
Source: Treatment*Baseline	p = 0.2687

**ANALYSIS OF VARIANCE (Final)**

Source: Treatment	p = 0.0011
Source: Center	p = 0.3371
Source: Treatment*Center	p = 0.5126
Source: Pre-treatment Level	p = 0.0000

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TABLE 5.4.3: Modified AFS Score by Center -European Patients

	Lubricoat Gel				Lactated Ringer's Solution			
	N	Pre	Post	LS Mean	N	Pre	Post	LS Mean
All Patients	38	1.66	0.91	.	39	2.00	1.95	.
Europe Center 21	12	0.99	0.77	0.98	14	1.96	2.28	2.25
Center 23	10	1.81	0.97	0.98	9	1.11	1.40	1.58
Center 25	5	1.31	0.52	0.64	8	3.03	2.20	1.91
Centers 27 and 29	11	2.42	1.18	1.04	8	2.07	1.74	1.68

ANALYSIS OF VARIANCE (Including Baseline Interaction Term)

Source: Treatment                    p = 0.0548  
Source: Center                        p = 0.8925  
Source: Treatment\*Center            p = 0.8939  
Source: Baseline Level              p = 0.0334  
Source: Treatment\*Baseline        p = 0.6360

ANALYSIS OF VARIANCE (Final)

Source: Treatment                    p = 0.0263  
Source: Center                        p = 0.9089  
Source: Treatment\*Center            p = 0.8866  
Source: Pre-treatment Level        p = 0.0335

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TABLE 5.4.4: Modified AFS Score (Log Transformed) by Center -All Patients

		Lubricote Gel				Lactated Ringer's Solution			
		N	Pre	Post	LS Mean	N	Pre	Post	LS Mean
All Patients		131	0.65	0.91	.	134	0.63	1.56	.
US	Center 02	21	0.65	1.01	1.01	18	0.39	1.97	2.22
	Center 03	6	0.07	0.93	1.36	5	1.13	3.77	3.21
	Centers 04 and 12	8	0.09	0.77	1.16	11	0.26	0.78	1.02
	Center 06	6	1.29	1.71	1.31	8	0.43	1.44	1.61
	Center 07	5	0.73	1.24	1.18	6	0.15	1.81	2.33
	Center 08	6	0.18	0.82	0.64	7	0.00	0.96	1.48
	Center 09	12	0.36	0.49	0.64	10	0.16	1.30	1.71
	Center 10	14	0.02	1.57	2.23	13	0.31	1.73	2.04
	Center 11	15	1.31	0.97	0.68	17	0.86	2.10	1.93
Europe	Center 21	12	0.58	0.57	0.60	14	1.38	1.61	1.19
	Center 23	10	1.31	0.64	0.39	9	0.78	0.96	0.88
	Center 25	5	1.22	0.47	0.27	8	2.88	1.86	0.89
	Centers 27 and 29	11	1.77	0.94	0.51	8	1.13	1.00	0.77

ANALYSIS OF VARIANCE (Including Baseline Interaction Term)

Source: Treatment	p = 0.0035
Source: Center	p = 0.0028
Source: Treatment*Center	p = 0.7149
Source: Baseline Level	p = 0.0000
Source: Treatment*Baseline	p = 0.9168

ANALYSIS OF VARIANCE (Final)

Source: Treatment	p = 0.0002
Source: Center	p = 0.0027
Source: Treatment*Center	p = 0.6989
Source: Pre-treatment Level	p = 0.0000

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Values are the means of log10(Modified AFS Score + 1)

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TABLE 5.4.5: Modified AFS Score (Rank-Transformed Intent-to-Treat Analysis) by Center

		Lubricote Gel				Lactated Ringer's Solution			
		N	Pre	Post	LS Mean	N	Pre	Post	LS Mean
All Patients		143	140.58	129.89	.	138	141.44	152.51	.
US	Center 02	24	141.77	140.94	140.66	20	119.68	176.05	183.66
	Center 03	6	85.00	114.08	134.06	5	180.60	213.10	198.97
	Centers 04, 5 and 12	10	100.35	149.00	163.50	12	123.58	126.54	132.75
	Center 06	6	162.42	168.83	161.19	8	146.56	154.06	152.08
	Center 07	5	153.90	139.40	134.80	6	113.00	168.33	178.32
	Center 08	6	115.58	111.67	120.73	7	67.50	122.79	149.00
	Center 09	12	108.17	81.63	93.34	10	100.90	124.50	138.80
	Center 10	14	73.79	149.46	173.44	13	116.38	157.73	166.51
	Center 11	19	165.37	151.42	142.73	17	149.62	163.47	160.40
Europe	Center 21	14	135.32	120.54	122.56	15	180.47	160.13	146.05
	Center 23	11	189.55	111.18	93.86	9	152.89	118.22	113.98
	Center 25	5	200.00	91.70	70.65	8	242.25	170.06	133.94
	Centers 27 and 29	11	208.77	119.91	95.73	8	166.19	117.38	108.39

ANALYSIS OF VARIANCE (Including Baseline Interaction Term)

Source: Treatment	p = 0.3707
Source: Center	p = 0.0292
Source: Treatment*Center	p = 0.8368
Source: Baseline Level	p = 0.0000
Source: Treatment*Baseline	p = 0.8276

ANALYSIS OF VARIANCE (Final)

Source: Treatment	p = 0.0172
Source: Center	p = 0.0265
Source: Treatment*Center	p = 0.8214
Source: Pre-treatment Level	p = 0.0000

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 Values are the means of rank scores with nonreturning patients assigned the worst possible score

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TABLE 5.6.1: Standard AFS Score

Variable	Lubricoat Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Baseline									
Right Ovary	128	1.77	(3.51)	0 to 16	132	1.87	(3.83)	0 to 16	0.830
Tube	128	1.45	(3.54)	0 to 16	128	1.26	(2.99)	0 to 16	0.647
Left Ovary	130	2.43	(4.50)	0 to 16	131	2.47	(4.47)	0 to 16	0.939
Tube	130	2.12	(4.25)	0 to 16	129	1.61	(3.72)	0 to 16	0.312
Total Right	126	3.10	(6.21)	0 to 32	128	3.09	(6.33)	0 to 32	0.983
Total Left	130	4.55	(8.21)	0 to 32	128	3.97	(7.43)	0 to 32	0.554
Average of R and L	131	3.85	(6.49)	0 to 32	134	3.88	(6.67)	0 to 32	0.978
Minimum of R and L	131	2.44	(5.32)	0 to 32	134	2.85	(6.04)	0 to 32	0.553
Second Look									
Right Ovary	128	1.84	(3.08)	0 to 16	132	2.95	(4.75)	0 to 16	0.026
Tube	128	1.44	(2.88)	0 to 16	128	2.75	(4.59)	0 to 16	0.007
Left Ovary	130	3.01	(4.80)	0 to 16	129	4.49	(6.21)	0 to 16	0.033
Tube	130	2.52	(4.67)	0 to 16	128	3.45	(5.16)	0 to 16	0.127
Total Right	126	3.16	(4.87)	0 to 24	128	5.66	(8.19)	0 to 32	0.003
Total Left	130	5.52	(8.73)	0 to 32	126	7.82	(10.42)	0 to 32	0.057
Average of R and L	131	4.37	(5.69)	0 to 24	134	7.19	(8.57)	0 to 32	0.002
Minimum of R and L	131	1.89	(3.61)	0 to 24	134	4.60	(7.95)	0 to 32	0.000

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 p values determined using Student's t test

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TABLE 5.6.2: Standard AFS Score (Minimum of Right and Left)

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
Mean Values									
Baseline	131	2.44	(5.32)	0 to 32	134	2.85	(6.04)	0 to 32	0.553
Second Look	131	1.89	(3.61)	0 to 24	134	4.60	(7.95)	0 to 32	0.000
Proportions	n	N	%		n	N	%		P
Baseline	109 / 131	83.2%			109 / 134	81.3%			0.749
	13 / 131	9.9%			8 / 134	6.0%			0.262
	7 / 131	5.3%			13 / 134	9.7%			0.245
	2 / 131	1.5%			4 / 134	3.0%			0.684
Second Look	119 / 131	90.8%			101 / 134	75.4%			0.001
	8 / 131	6.1%			13 / 134	9.7%			0.364
	3 / 131	2.3%			13 / 134	9.7%			0.018
	1 / 131	0.8%			7 / 134	5.2%			0.066

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 p values determined using Student's t test and the Fisher exact test

LIFECORE, INC.  
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TABLE 6.1: Adverse Events (part 1)

Variable	Lubrocoat Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
BODY AS A WHOLE							
ALL	143	/ 143	100.0%	137	/ 138	99.3%	0.491
ABDOMEN ENLARGED	1	/ 143	0.7%	2	/ 138	1.4%	0.617
ALLERGIC REACTION	3	/ 143	2.1%	10	/ 138	7.2%	0.048
ASTHENIA	7	/ 143	4.9%	4	/ 138	2.9%	0.541
CHILLS	3	/ 143	2.1%	2	/ 138	1.4%	1.000
FEVER	25	/ 143	17.5%	19	/ 138	13.8%	0.416
FLU SYNDROME	2	/ 143	1.4%	3	/ 138	2.2%	0.680
HEADACHE	45	/ 143	31.5%	37	/ 138	26.8%	0.432
INCISION INFLAMMATION	8	/ 143	5.6%	8	/ 138	5.8%	1.000
INCISION OPENING	7	/ 143	4.9%	5	/ 138	3.6%	0.770
INCISION PAIN	9	/ 143	6.3%	13	/ 138	9.4%	0.379
INFECTION	6	/ 143	4.2%	2	/ 138	1.4%	0.283
ACCIDENTAL INJURY	1	/ 143	0.7%	1	/ 138	0.7%	1.000
NECK RIGIDITY	0	/ 143	0.0%	1	/ 138	0.7%	0.491
PAIN	122	/ 143	85.3%	111	/ 138	80.4%	0.342
ABDOMINAL PAIN	39	/ 143	27.3%	42	/ 138	30.4%	0.599
BACK PAIN	13	/ 143	9.1%	7	/ 138	5.1%	0.247
CHEST PAIN	3	/ 143	2.1%	2	/ 138	1.4%	1.000
NECK PAIN	0	/ 143	0.0%	1	/ 138	0.7%	0.491
PELVIC PAIN	3	/ 143	2.1%	3	/ 138	2.2%	1.000
UNEXPECTED BENEFIT	1	/ 143	0.7%	0	/ 138	0.0%	1.000
CARDIOVASCULAR							
ALL	15	/ 143	10.5%	15	/ 138	10.9%	1.000
HEMORRHAGE	3	/ 143	2.1%	4	/ 138	2.9%	0.719
HYPERTENSION	1	/ 143	0.7%	0	/ 138	0.0%	1.000
HYPOTENSION	0	/ 143	0.0%	1	/ 138	0.7%	0.491
MIGRAINE	1	/ 143	0.7%	1	/ 138	0.7%	1.000
PHLEBITIS	1	/ 143	0.7%	0	/ 138	0.0%	1.000
SYNCOPE	2	/ 143	1.4%	1	/ 138	0.7%	1.000
TACHYCARDIA	4	/ 143	2.8%	7	/ 138	5.1%	0.371
VASODILATATION	3	/ 143	2.1%	4	/ 138	2.9%	0.719

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TABLE 6.2: Adverse Events (part 2)

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
<b>DIGESTIVE</b>							
ALL	106	/ 143	74.1%	100	/ 138	72.5%	0.788
ANOREXIA	0	/ 143	0.0%	1	/ 138	0.7%	0.491
CONSTIPATION	47	/ 143	32.9%	56	/ 138	40.6%	0.216
DIARRHEA	6	/ 143	4.2%	2	/ 138	1.4%	0.283
DYSPEPSIA	14	/ 143	9.8%	0	/ 138	0.0%	1.000
ERUPTION	1	/ 143	0.7%	35	/ 138	25.4%	0.891
FLATULENCE	35	/ 143	24.5%	0	/ 138	0.0%	0.498
GASTRITIS	2	/ 143	1.4%	0	/ 138	0.0%	1.000
GASTROENTERITIS	1	/ 143	0.7%	0	/ 138	0.0%	1.000
GASTROINTESTINAL HEMORRHAGE	1	/ 143	0.7%	1	/ 138	0.7%	0.491
RECTAL HEMORRHAGE	0	/ 143	0.0%	1	/ 138	0.7%	0.623
ILEUS	3	/ 143	2.1%	1	/ 138	0.7%	0.491
INTESTINAL PERFORATION	0	/ 143	0.0%	65	/ 138	47.1%	0.905
NAUSEA	66	/ 143	46.2%	1	/ 138	0.7%	1.000
NAUSEA AND VOMITING	1	/ 143	0.7%	0	/ 138	0.0%	1.000
PANCREATITIS	1	/ 143	0.7%	2	/ 138	1.4%	0.617
RECTAL DISORDER	0	/ 143	0.0%	1	/ 138	0.7%	0.491
ABNORMAL STOOLS	1	/ 143	0.7%	0	/ 138	0.0%	1.000
TOOTH CAVIES	4	/ 143	2.8%	0	/ 138	0.0%	0.123
TOOTH DISORDER	13	/ 143	9.1%	14	/ 138	10.1%	0.841
VOMITING							
<b>HEMIC AND LYMPHATIC</b>							
ALL	19	/ 143	13.3%	16	/ 138	11.6%	0.720
ANEMIA	12	/ 143	8.4%	13	/ 138	9.4%	0.835
IRON DEFICIENCY ANEMIA	5	/ 143	3.5%	2	/ 138	1.4%	0.448
ECCHYMOSIS	1	/ 143	0.7%	1	/ 138	0.7%	1.000
LEUKOCYTOSIS	1	/ 143	0.7%	0	/ 138	0.0%	1.000
<b>METABOLIC AND NUTRITIONAL</b>							
ALL	4	/ 143	2.8%	1	/ 138	0.7%	0.371
PERIPHERAL EDEMA	1	/ 143	0.7%	1	/ 138	0.7%	1.000
HYPOKALEMIA	2	/ 143	1.4%	0	/ 138	0.0%	0.498
SGPT INCREASED	1	/ 143	0.7%	0	/ 138	0.0%	1.000

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TABLE 6.3: Adverse Events (part 3)

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
MUSCULO-SKELETAL							
ALL	3 / 143	2.1%		3 / 138	2.2%		1.000
ARTHRITIS	1 / 143	0.7%		0 / 138	0.0%		1.000
LEG CRAMPS	2 / 143	1.4%		1 / 138	0.7%		1.000
MYALGIA	0 / 143	0.0%		2 / 138	1.4%		0.240
NERVOUS SYSTEM							
ALL	37 / 143	25.9%		40 / 138	29.0%		0.594
ANXIETY	1 / 143	0.7%		4 / 138	2.9%		0.207
CONFUSION	1 / 143	0.7%		0 / 138	0.0%		1.000
CONVULSION	1 / 143	0.7%		0 / 138	0.0%		1.000
DEPRESSION	15 / 143	10.5%		13 / 138	9.4%		0.843
DIZZINESS	0 / 143	0.0%		1 / 138	0.7%		0.491
ABNORMAL GAIT	1 / 143	0.7%		0 / 138	0.0%		1.000
HALLUCINATIONS	1 / 143	0.7%		1 / 138	0.7%		1.000
HYPERTONIA	1 / 143	0.7%		2 / 138	1.4%		0.240
HYPERESTHESIA	0 / 143	0.0%		22 / 138	15.9%		0.738
INSOMNIA	20 / 143	14.0%		0 / 138	0.0%		1.000
NEURALGIA	1 / 143	0.7%		1 / 138	0.7%		0.491
NEURITIS	0 / 143	0.0%		1 / 138	0.7%		0.491
INCREASED SALIVATION	0 / 143	0.0%		1 / 138	0.7%		1.000
SOMNOLENCE	1 / 143	0.7%					

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TABLE 6.4: Adverse Events (part 4)

Variable	Lubricote Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
RESPIRATORY							
ALL	30	143	21.0%	26	138	18.8%	0.765
ASTHMA	1	143	0.7%	0	138	0.0%	1.000
ATELECTASIS	3	143	2.1%	0	138	0.0%	0.248
BRONCHITIS	0	143	0.0%	1	138	0.7%	0.491
COUGH INCREASED	11	143	7.7%	8	138	5.8%	0.637
DYSPNEA	1	143	0.7%	1	138	0.7%	1.000
PLEURAL EFFUSION	1	143	0.7%	1	138	0.7%	0.491
PULMONARY EMBOLUS	0	143	0.0%	1	138	0.7%	0.491
EPISTAXIS	0	143	0.0%	0	138	0.0%	1.000
HICCUP	1	143	0.7%	0	138	0.0%	1.000
HYPERVENTILATION	2	143	1.4%	7	138	5.1%	1.000
INFECTION	8	143	5.6%	1	138	0.7%	0.491
LARYNGITIS	0	143	0.0%	4	138	2.9%	0.441
LUNG DISORDER	2	143	1.4%	5	138	3.6%	0.770
PHARYNGITIS	7	143	4.9%	6	138	4.3%	1.000
RHINITIS	6	143	4.2%	0	138	0.0%	1.000
STRIDOR	1	143	0.7%				
SKIN							
ALL	13	143	9.1%	13	138	9.4%	1.000
ACNE	0	143	0.0%	1	138	0.7%	0.491
NAIL DISORDER	1	143	0.7%	0	138	0.0%	1.000
PRURITUS	8	143	5.6%	10	138	7.2%	0.632
RASH	2	143	1.4%	2	138	1.4%	1.000
VESICULOBULLOUS RASH	0	143	0.0%	1	138	0.7%	0.491
SKIN DISCOLORATION	1	143	0.7%	0	138	0.0%	1.000
SWEATING	2	143	1.4%	1	138	0.7%	1.000
URTICARIA	0	143	0.0%	1	138	0.7%	0.491
SPECIAL SENSES							
ALL	2	143	1.4%	1	138	0.7%	1.000
EAR DISORDER	0	143	0.0%	1	138	0.7%	0.491
EAR PAIN	1	143	0.7%	0	138	0.0%	1.000
ABNORMAL VISION	1	143	0.7%	0	138	0.0%	1.000

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TABLE 6.5: Adverse Events (part 5)

Variable	Lubricoat Gel			Lactated Ringer's Solution			P
	n	N	%	n	N	%	
UROGENITAL							
ALL	44	/ 143	30.8%	40	/ 138	29.0%	0.795
AMENORRHEA	0	/ 143	0.0%	1	/ 138	0.7%	0.491
CYSTITIS	5	/ 143	3.5%	1	/ 138	0.7%	0.214
DYSMENORRHEA	25	/ 143	17.5%	22	/ 138	15.9%	0.752
DYSURIA	3	/ 143	2.1%	4	/ 138	2.9%	0.719
ENDOMETRIAL DISORDER	0	/ 143	0.0%	1	/ 138	0.7%	0.491
GASTROINTESTINAL DISORDER	0	/ 143	0.0%	1	/ 138	0.7%	1.000
VAGINAL HEMORRHAGE	1	/ 143	0.7%	1	/ 138	0.7%	0.491
URINARY INCONTINENCE	0	/ 143	0.0%	3	/ 138	2.2%	0.501
URINARY TRACT INFECTION	6	/ 143	4.2%	1	/ 138	0.7%	0.491
LEUKORRHEA	0	/ 143	0.0%	0	/ 138	0.0%	0.123
MENORRHAGIA	4	/ 143	2.8%	2	/ 138	1.4%	1.000
MENSTRUAL DISORDER	3	/ 143	2.1%	4	/ 138	2.9%	0.719
VAGINAL MONILITASIS	3	/ 143	2.1%	1	/ 138	0.7%	0.491
OLIGURIA	0	/ 143	0.0%	2	/ 138	1.4%	0.617
BREAST PAIN	1	/ 143	0.7%	0	/ 138	0.0%	1.000
RECTAL DISORDER	1	/ 143	0.7%	1	/ 138	0.7%	1.000
SALPINGITIS	1	/ 143	0.7%	0	/ 138	0.0%	1.000
URINARY FREQUENCY	1	/ 143	0.7%	2	/ 138	1.4%	0.240
URINARY RETENTION	0	/ 143	0.0%	1	/ 138	0.7%	0.491
VAGINITIS	0	/ 143	0.0%	1	/ 138	0.7%	0.491
VULVOVAGINAL DISORDER	0	/ 143	0.0%	0	/ 138	0.0%	1.000
VULVOVAGINITIS	1	/ 143	0.7%				

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TABLE 7.1: Baseline Laboratory Values

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
BUN (mg/dL)	142	11.15	(3.14)	5.0 to 22.0	137	11.57	(3.28)	4.8 to 21.8	0.277
Creatinine (mg/dL)	143	0.80	(0.14)	0.5 to 1.3	136	0.79	(0.14)	0.5 to 1.2	0.760
Phosphorus (mg/dL)	140	3.50	(0.58)	2.2 to 5.4	131	3.55	(0.58)	1.7 to 5.3	0.466
Calcium (mg/dL)	142	9.38	(0.52)	7.2 to 10.8	135	9.43	(0.53)	8.3 to 11.5	0.418
Uric Acid (mg/dL)	140	3.79	(1.07)	1.3 to 7.2	131	3.80	(1.06)	1.8 to 7.0	0.956
Total Protein (gm/dL)	138	7.24	(0.56)	4.7 to 8.4	133	7.33	(0.56)	5.1 to 8.7	0.169
Albumin (gm/dL)	143	4.26	(0.43)	2.6 to 5.3	137	4.29	(0.39)	3.2 to 5.4	0.580
Total Bilirubin (mg/dL)	143	0.52	(0.24)	0.2 to 1.9	137	0.52	(0.24)	0.1 to 1.8	0.908
SGOT (IU/L)	143	20.2	(10.8)	8 to 119	137	21.8	(10.5)	7 to 85	0.195
SGPT (IU/L)	141	19.5	(11.8)	3 to 77	134	22.4	(14.7)	7 to 127	0.068
Alkaline Phosphatase (IU/L)*	143	74.8	(39.9)	25 to 246	136	77.2	(42.0)	29 to 258	0.631
Sodium (mEq/L)	143	140.0	(2.1)	135 to 148	138	139.9	(2.5)	132 to 148	0.595
Potassium (mEq/L)	143	4.13	(0.30)	3.3 to 4.9	138	4.20	(0.42)	3.1 to 5.8	0.158
Chloride (mEq/L)	142	105.2	(3.7)	96 to 126	138	105.2	(4.2)	97 to 124	0.891
Hemoglobin (g/dL)	141	12.72	(1.40)	8.0 to 15.3	137	12.85	(1.24)	8.6 to 16.0	0.412
Hematocrit (%)	141	37.9	(4.1)	24.0 to 46.5	137	38.4	(3.6)	26.4 to 48.4	0.332
RBC (mil/cu.mm)	141	4.32	(0.39)	3.38 to 5.30	137	4.36	(0.43)	3.44 to 5.53	0.383
WBC (thous/cu.mm)	141	6.62	(1.85)	3.6 to 14.8	137	6.83	(2.25)	2.8 to 18.1	0.402
Neutrophils (%)	132	57.9	(8.7)	29.6 to 76.9	125	59.6	(11.1)	31.0 to 89.0	0.181
Lymphocytes (%)	132	31.7	(7.3)	17.0 to 50.9	126	30.2	(9.6)	7.0 to 53.0	0.152
Monocytes (%)	132	7.0	(2.1)	2.0 to 14.0	126	6.8	(2.2)	1.7 to 13.0	0.583
Eosinophils (%)	132	2.4	(1.8)	0.0 to 11.3	126	2.3	(2.1)	0.0 to 10.8	0.882
Basophils (%)	132	0.7	(0.4)	0.0 to 2.0	126	0.7	(0.5)	0.0 to 3.0	0.859

Variable	n	N	%	n	N	%	P
Clinically Significant	0 / 137	0.0%		1 / 134	0.7%		0.494
Pregnancy	0 / 143	0.0%		0 / 137	0.0%		0.494

DIRECTORY: E:\ETHICON\PTL13\PMA\ FILE: TBLABS.PRT February 24, 1999  
 p values determined using Student's t test or the Fisher exact test  
 \* Alkaline Phosphatase values could not be adequately transformed for some centers

LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 7.2: Visit 1 Laboratory Values

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
BUN (mg/dL)	134	6.93	(2.66)	1.0 to 14.0	128	7.17	(2.87)	3.0 to 18.0	0.494
Creatinine (mg/dL)	135	0.73	(0.14)	0.4 to 1.2	131	0.70	(0.14)	0.3 to 1.0	0.200
Phosphorus (mg/dL)	122	3.11	(0.79)	1.4 to 5.3	122	3.20	(0.66)	1.8 to 5.1	0.301
Calcium (mg/dL)	133	8.64	(0.68)	7.1 to 10.5	131	8.79	(0.84)	7.3 to 13.3	0.114
Uric Acid (mg/dL)	125	3.09	(1.00)	1.1 to 6.4	123	3.14	(1.10)	1.2 to 6.6	0.661
Total Protein (gm/dL)	128	5.98	(0.63)	4.3 to 7.3	126	6.12	(0.64)	4.6 to 7.8	0.071
Albumin (gm/dL)	134	3.34	(0.49)	2.3 to 4.7	131	3.42	(0.52)	2.4 to 4.8	0.190
Total Bilirubin (mg/dL)	130	0.58	(0.43)	0.2 to 3.7	125	0.53	(0.23)	0.2 to 1.3	0.285
SGOT (IU/L)	133	20.1	(9.6)	5 to 74	129	22.1	(12.1)	5 to 85	0.140
SGPT (IU/L)	126	17.4	(9.8)	1 to 56	121	20.1	(13.4)	0 to 93	0.070
Alkaline Phosphatase (IU/L)*	131	70.6	(40.8)	23 to 252	129	70.3	(41.8)	28 to 282	0.951
Sodium (mEq/L)	135	139.2	(2.4)	126 to 145	131	139.5	(2.2)	134 to 149	0.200
Potassium (mEq/L)	135	3.76	(0.32)	2.9 to 4.5	131	3.76	(0.34)	2.8 to 4.8	0.996
Chloride (mEq/L)	136	105.6	(4.1)	94 to 128	130	105.6	(3.3)	99 to 125	0.934
Hemoglobin (g/dL)	141	10.68	(1.73)	6.3 to 14.6	136	10.72	(1.61)	5.2 to 13.6	0.860
Hematocrit (%)	141	31.8	(5.1)	19.2 to 42.0	136	32.1	(4.8)	15.9 to 41.0	0.693
RBC (mil/cu.mm)	139	3.63	(0.57)	2.20 to 5.10	135	3.63	(0.55)	1.85 to 5.03	0.966
WBC (thous/cu.mm)	139	8.89	(3.19)	3.5 to 19.9	136	7.87	(2.50)	3.5 to 15.8	0.004
Neutrophils (%)	130	70.5	(9.6)	50.7 to 94.0	131	67.6	(9.6)	44.1 to 89.3	0.016
Lymphocytes (%)	131	19.7	(7.6)	3.0 to 37.0	131	21.9	(8.1)	4.9 to 44.1	0.026
Monocytes (%)	131	7.0	(2.3)	1.0 to 13.4	132	7.1	(2.2)	2.7 to 14.4	0.584
Eosinophils (%)	129	2.2	(2.4)	0.0 to 20.0	132	2.6	(2.2)	0.0 to 12.1	0.186
Basophils (%)	128	0.4	(0.4)	0.0 to 2.0	131	0.6	(0.5)	0.0 to 5.0	0.026

Variable	n	N	%	n	N	%	P
Clinically Significant	9	138	6.5%	10	137	7.3%	0.817
Pregnancy	.	0	.	.	0	.	0.817

DIRECTORY: E:\ETHICON\PTL13\PMA\ FILE: T1LABS.PRT February 24, 1999  
 p values determined using Student's t test or the Fisher exact test  
 \* Alkaline Phosphatase values could not be adequately transformed for some centers

LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 7.3: Visit 2 Laboratory Values

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
BUN (mg/dL)	128	11.78	(3.18)	6.0 to 21.0	129	12.22	(4.72)	6.0 to 51.0	0.386
Creatinine (mg/dL)	129	0.77	(0.14)	0.4 to 1.4	129	0.79	(0.23)	0.5 to 2.9	0.428
Phosphorus (mg/dL)	125	3.77	(0.57)	2.4 to 6.1	125	3.70	(0.59)	1.6 to 5.2	0.332
Calcium (mg/dL)	126	9.51	(0.42)	8.6 to 10.9	126	9.58	(0.44)	8.5 to 10.6	0.194
Uric Acid (mg/dL)	127	3.81	(1.11)	1.1 to 10.6	126	3.81	(1.09)	1.4 to 8.0	0.987
Total Protein (gm/dL)	123	7.32	(0.41)	6.1 to 8.4	125	7.35	(0.45)	5.5 to 8.5	0.595
Albumin (gm/dL)	128	4.24	(0.37)	2.9 to 5.3	127	4.26	(0.36)	3.3 to 5.2	0.647
Total Bilirubin (mg/dL)	128	0.49	(0.23)	0.2 to 1.6	128	0.46	(0.17)	0.2 to 0.9	0.362
SGOT (IU/L)	129	18.2	(7.9)	6 to 61	129	20.8	(10.0)	8 to 75	0.024
SGPT (IU/L)	128	21.9	(16.9)	0 to 126	129	23.3	(14.5)	5 to 93	0.494
Alkaline Phosphatase (IU/L)*	129	84.5	(47.3)	23 to 252	124	80.5	(39.5)	28 to 258	0.497
Sodium (mEq/L)	130	139.7	(2.3)	132 to 145	129	140.3	(2.2)	134 to 146	0.023
Potassium (mEq/L)	130	4.43	(0.68)	3.5 to 9.5	129	4.36	(0.48)	3.6 to 7.1	0.332
Chloride (mEq/L)	130	103.7	(3.2)	97 to 112	128	104.4	(3.3)	91 to 113	0.086
Hemoglobin (g/dL)	126	12.28	(2.79)	8.9 to 39.0	129	12.23	(1.33)	7.7 to 15.3	0.865
Hematocrit (%)	126	36.6	(6.1)	26.1 to 87.0	129	36.6	(3.8)	24.2 to 45.0	0.894
RBC (mil/cu.mm)	126	4.13	(0.44)	2.93 to 5.20	128	4.16	(0.46)	2.81 to 5.68	0.627
WBC (thous/cu.mm)	126	7.61	(2.48)	3.0 to 18.6	129	7.26	(1.94)	2.7 to 14.7	0.215
Neutrophils (%)	121	62.3	(9.9)	36.8 to 92.0	125	60.4	(9.3)	40.0 to 84.0	0.116
Lymphocytes (%)	122	27.4	(8.7)	4.0 to 54.2	124	28.9	(8.3)	13.0 to 50.0	0.169
Monocytes (%)	122	6.6	(2.1)	0.2 to 14.0	124	6.5	(2.3)	1.0 to 13.5	0.663
Eosinophils (%)	121	2.8	(1.7)	0.0 to 10.0	123	3.3	(2.5)	0.6 to 14.8	0.068
Basophils (%)	120	0.7	(0.5)	0.0 to 3.0	124	0.7	(0.5)	0.0 to 2.0	0.551

Variable	n	N	%	n	N	%	P
Clinically Significant	5	128	3.9%	5	129	3.9%	1.000
Pregnancy	. /	0	. %	. /	0	. %	1.000

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 p values determined using Student's t test or the Fisher exact test  
 \* Alkaline Phosphatase values could not be adequately transformed for some centers

LIFECORE, INC.  
 Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
 Protocol PTL-0013 and PTL-0022

TABLE 7.4: Visit 3 Laboratory Values

Variable	Lubricote Gel				Lactated Ringer's Solution				P
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	
BUN (mg/dL)	129	10.99	(2.54)	5.0 to 19.0	130	11.30	(2.96)	6.0 to 24.0	0.375
Creatinine (mg/dL)	130	0.77	(0.12)	0.5 to 1.1	130	0.76	(0.14)	0.4 to 1.1	0.813
Phosphorus (mg/dL)	126	3.48	(0.52)	2.3 to 5.2	129	3.54	(0.52)	2.3 to 4.7	0.416
Calcium (mg/dL)	128	9.40	(0.41)	8.6 to 10.7	129	9.43	(0.42)	8.2 to 10.5	0.560
Uric Acid (mg/dL)	128	3.80	(1.01)	1.7 to 7.4	129	3.79	(1.01)	1.6 to 7.8	0.928
Total Protein (gm/dL)	123	7.26	(0.49)	5.9 to 8.8	127	7.27	(0.45)	6.0 to 8.8	0.834
Albumin (gm/dL)	129	4.28	(0.33)	3.3 to 5.1	130	4.25	(0.35)	3.3 to 5.0	0.486
Total Bilirubin (mg/dL)	129	0.51	(0.23)	0.1 to 1.6	129	0.50	(0.18)	0.1 to 1.2	0.624
SGOT (IU/L)	129	18.2	(8.0)	7 to 75	129	20.3	(11.9)	5 to 106	0.092
SGPT (IU/L)	127	18.1	(10.9)	1 to 67	127	19.2	(13.0)	3 to 120	0.444
Alkaline Phosphatase (IU/L)*	129	79.1	(40.7)	30 to 228	128	81.3	(42.6)	28 to 226	0.670
Sodium (mEq/L)	130	140.2	(2.3)	133 to 151	130	140.3	(2.3)	135 to 146	0.713
Potassium (mEq/L)	129	4.15	(0.32)	3.4 to 5.3	129	4.16	(0.36)	3.4 to 5.2	0.776
Chloride (mEq/L)	126	105.4	(5.6)	97 to 156	126	105.2	(3.2)	95 to 115	0.668
Hemoglobin (g/dL)	133	12.64	(1.30)	7.2 to 15.1	132	12.63	(1.19)	8.1 to 15.2	0.961
Hematocrit (%)	133	37.8	(3.6)	24.2 to 45.5	134	37.8	(3.1)	25.9 to 44.4	0.945
RBC (mil/cu.mm)	133	4.31	(0.38)	2.84 to 5.26	132	4.33	(0.38)	3.30 to 5.62	0.777
WBC (thous/cu.mm)	133	6.87	(2.01)	3.7 to 13.2	132	6.58	(2.26)	2.2 to 13.0	0.262
Neutrophils (%)	131	58.8	(9.3)	36.0 to 78.4	127	57.9	(9.9)	32.0 to 81.0	0.453
6 to 57.4		0.441							
Monocytes (%)	130	7.1	(2.3)	2.7 to 15.2	128	7.0	(2.3)	1.0 to 14.7	0.628
Eosinophils (%)	130	2.5	(1.6)	0.0 to 12.1	128	2.7	(2.2)	0.0 to 13.1	0.425
Basophils (%)	129	0.7	(0.5)	0.0 to 3.0	126	0.7	(0.5)	0.0 to 2.0	0.412

Variable	n	N	%	n	N	%	P
Clinically Significant	3	127	2.4%	1	127	0.8%	0.622
Pregnancy	1	131	0.8%	0	133	0.0%	0.496

DIRECTORY: E:\ETHICON\PTL13\PMA\ FILE: T3LABS.PRT February 24, 1999  
 p values determined using Student's t test or the Fisher exact test  
 \* Alkaline Phosphatase values could not be adequately transformed for some centers

ed for some centers

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Lubricote Gel versus Lactated Ringer's solution for Prevention of Adhesions  
Protocol PTL-0013 and PTL-0022

TABLE 8.1: Shift table for BUN

			Lubricote Gel			Lactated Ringer's Solution			P	
			Post-treatment			Post-treatment				
			L	N	H	L	N	H		
Baseline vs Day 3		Pre-treatment	H	.	.	.	.	1	0.909	
			N	47	77	.	44	71		
			L	10	.	.	11	.		
Baseline vs Day 7-28		Pre-treatment	H	.	.	.	.	1	0.034	
			N	1	118	.	9	107		
			L	6	2	.	6	5		
Baseline vs Second Look		Pre-treatment	H	.	.	.	.	1	0.555	
			N	7	113	.	3	115		
			L	5	3	.	8	3		

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Fisher's exact test

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Protocol PTL-0013 and PTL-0022

TABLE 8.2: Shift table for Creatinine

		Lubricat Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	.	.	1	.	0.920	
		N	10	113	.	12	105	.	
		L	11	1	.	10	1	.	
Baseline vs Day 7-28	Pre-treatment	H	.	.	.	1	.	0.920	
		N	7	108	1	5	110	1	
		L	8	5	.	8	3	.	
Baseline vs Second Look	Pre-treatment	H	.	.	.	1	.	0.360	
		N	2	117	.	7	110	.	
		L	8	3	.	9	2	.	

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Fisher's exact test

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TABLE 8.3: Shift table for Phosphorus

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	2	4	1	13	6	.298	
		N	24	79	3	92	2		
		L	2	4	.	4	.		
Baseline vs Day 7-28	Pre-treatment	H	.	6	1	2	7	.886	
		N	2	102	6	102	6		
		L	.	5	1	2	.		
Baseline vs Second Look	Pre-treatment	H	.	6	1	1	6	.947	
		N	1	109	2	107	4		
		L	.	5	.	3	.		

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TABLE 8.4: Shift table for Calcium

		Lubricote Gel			Lactated Ringer's Solution			p	
		Post-treatment			Post-treatment				
		H	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	2	.	.	3	1	0.632
		N	51	74	.	42	79	1	
		L	4	1	.	2	.	.	
Baseline vs Day 7-28	Pre-treatment	H	.	1	1	.	2	1	0.664
		N	.	119	1	.	111	3	
		L	.	.	.	.	.	.	
Baseline vs Second Look	Pre-treatment	H	.	1	1	.	3	1	0.340
		N	.	121	1	.	118	1	
		L	1	4	.	1	1	.	

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p values determined using 2x9 Fisher's exact test

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Fisher's exact test

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TABLE 8.5: Shift table for Uric Acid

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	1	1	.	1	1	0.695
		N	18	86	.	15	86	.	
		L	13	3	.	15	.	.	
Baseline vs Day 7-28	Pre-treatment	H	.	2	.	.	1	1	0.660
		N	5	98	1	2	100	.	
		L	13	6	.	14	3	.	
Baseline vs Second Look	Pre-treatment	H	.	1	1	.	1	1	0.959
		N	6	101	.	3	100	.	
		L	11	6	.	11	5	.	

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TABLE 8.6: Shift table for Total Protein

		Lubricote Gel			Lactated Ringer's Solution					
		Post-treatment			Post-treatment					
		L	N	H	L	N	H			
Baseline vs Day 3	Pre-treatment	H	1	3	.	3	3	.	0.340	
		N	71	47	.	56	58	.		
		L	4	2	.	4	.	.		
Baseline vs Day 7-28	Pre-treatment	H	.	3	1	.	5	1	0.598	
		N	.	108	4	3	106	5		
		L	.	6	1	.	4	.		
		H	.	1	2	.	4	2		
		1	3	.						

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p values determined using 2x9 Fisher's exact test

Fisher's exact test

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TABLE 8.7: Shift table for Albumin

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		H	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	1	6	.	2	6	1	0.889
		N	74	46	.	65	50	1	
		L	6	1	.	5	.	.	
Baseline vs Day 7-28	Pre-treatment	H	.	1	6	.	5	4	0.221
		N	1	112	1	4	106	2	
		L	3	4	.	5	.	.	
Baseline vs Second Look	Pre-treatment	H	.	3	4	.	6	3	0.549
		N	1	111	2	5	107	3	
		L	2	6	.	2	3	.	

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TABLE 8.8: Shift table for Total Bilirubin

		Lubricote Gel			Lactated Ringer's Solution		
		Post-treatment			Post-treatment		
		L	N	H	L	N	H
Baseline vs Day 3	Pre-treatment	H	.	5	.	1	2
		N	:	123	2	117	2
		L	:	.	.	2	.
Baseline vs Day 7-28	Pre-treatment	H	.	2	3	3	.
		N	:	121	2	122	.
		L	:	.	.	1	.
Baseline vs Second Look	Pre-treatment	H	.	3	2	3	.
		N	:	123	1	122	.
		L	:	.	.	2	.

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 Protocol PTL-0013 and PTL-0022

TABLE 8.9: Shift table for SGOT

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	4	.	.	3	0.377	
		N	.	122	6	2	113	10	
		L	1	.	.	.	.	.	
Baseline vs Day 7-28	Pre-treatment	H	.	4	.	.	2	0.458	
		N	2	120	2	2	117	5	
		L	1	.	.	.	.	.	
Baseline vs Second Look	Pre-treatment	H	.	3	1	.	2	1.000	
		N	2	120	2	1	120	3	
		L	1	.	.	.	.	.	

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Fisher's exact test

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TABLE 8.10: Shift table for SGPT

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		H	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	4	2		8	5	0.226	
		N	3	108	3	2	98		
		L	3	1	.	.	.		
Baseline vs Day 7-28	Pre-treatment	H	4	2		7	7	0.191	
		N	2	106	9	4	95		
		L	1	2	1	.	.		
Baseline vs Second Look	Pre-treatment	H	2	4		10	4	0.015	
		N	4	109	3	1	108		
		L	1	3	.	.	.		

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TABLE 8.11: Shift table for Alkaline Phosphatase

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	2	1	.	1	0.543	
		N	6	117	.	4	117		
		L	4	1	.	1	3		
Baseline vs Day 7-28	Pre-treatment	H	.	3	.	.	1	0.235	
		N	1	114	5	1	116		
		L	3	3	.	2	2		
Baseline vs Second Look	Pre-treatment	H	.	1	.	2	117	0.067	
		N	2	119	1	.	5		
		L	5	1	.				

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TABLE 8.12: Shift table for Sodium

		Pre-treatment	Lubricat Gel			Lactated Ringer's Solution			P
			L	N	H	L	N	H	
Baseline vs Day 3		H	.	.	.	.	.	1	
Baseline vs Day 3		N	2	133	.	2	126	.	0.416
Baseline vs Day 3		L	.	.	.	.	2	.	
Baseline vs Day 7-28		H	.	1	.	.	1	.	
Baseline vs Day 7-28		N	2	127	.	1	126	.	1.000
Baseline vs Day 7-28		L	.	.	.	.	1	.	
Baseline vs Second Look		H	.	.	1	.	.	1	
Baseline vs Second Look		N	1	127	1	.	128	.	1.000
Baseline vs Second Look		L	.	.	.	.	1	.	

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TABLE 8.13: Shift table for Potassium  
Lactated Ringer's Solution

		Post-treatment			Post-treatment			P	
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	.	.	2	1	.	0.758
		N	24	108	.	21	105	.	
		L	1	2	.	1	1	.	
Baseline vs Day 7-28	Pre-treatment	H	.	.	.	3	.	.	0.264
		N	.	118	9	.	119	5	
		L	.	3	.	.	2	.	
Baseline vs Second Look	Pre-treatment	H	.	.	.	3	.	.	0.393
		N	1	126	.	3	121	.	
		L	1	1	.	1	1	.	

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TABLE 8.14: Shift table for Chloride

		Lubricat Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	12	7	.	12	6	0.615
		N	2	103	10	.	97	15	
		L	.	1	.	.	.	.	
Baseline vs Day 7-28	Pre-treatment	H	.	11	7	.	11	8	0.211
		N	1	107	1	1	101	7	
		L	.	2	.	.	.	.	
Baseline vs Second Look	Pre-treatment	H	.	11	5	.	11	7	0.942
		N	.	101	8	1	98	9	
		L	.	1	.	.	.	.	

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TABLE 8.15: Shift table for Hemoglobin

		Lubricoat Gel			Lactated Ringer's Solution			p-value
		Post-treatment			Post-treatment			
Baseline vs Day 3	Pre-treatment	H	.	.	.	.	.	0.291
		N	60	37	.	71	33	
		L	41	1	.	31	.	
Baseline vs Day 7-28	Pre-treatment	H	.	.	.	19	79	0.619
		N	21	66	1	26	4	
		L	32	4	.	.	.	
Baseline vs Second Look	Pre-treatment	H	.	.	.	11	91	0.244
		N	5	87	.	23	7	
		L	33	7	.	.	.	

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TABLE 8.16: Shift table for Hematocrit

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	2	.	1	.	0.161	
		N	71	30	.	79	32		
		L	35	1	.	21	2		
Baseline vs Day 7-28	Pre-treatment	H	.	1	1	.	1	0.426	
		N	23	66	1	28	76		
		L	26	6	.	16	7		
Baseline vs Second Look	Pre-treatment	H	.	2	.	.	1	0.471	
		N	8	88	.	10	99		
		L	20	14	.	12	11		

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TABLE 8.17: Shift table for RBC

			Lubricote Gel			Lactated Ringer's Solution			P
			Post-treatment			Post-treatment			P
			L	N	H	L	N	H	
						4	4	.	
			H	3	3	.			
			27	2	.				
Baseline vs Day 7-28	Pre-treatment	H	2	1	4	.	3	3	0.586
		N	18	70	2	25	66	1	
		L	23	4	.	21	8	.	
Baseline vs Second Look	Pre-treatment	H	.	2	5	1	2	5	0.964
		N	8	84	1	11	84	.	
		L	18	14	.	14	15	.	

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TABLE 8.18: Shift table for WBC

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	1	6	.	6	2	0.027
		N	3	96	(29)	4	102	15	
		L	1	2	1	.	6	.	
Baseline vs Day 7-28	Pre-treatment	H	.	2	6	.	5	3	0.245
		N	2	98	(13)	1	109	5	
		L	1	2	.	1	4	.	
Baseline vs Second Look	Pre-treatment	H	.	5	3	.	6	2	0.313
		N	3	112	5	12	101	6	
		L	1	3	.	2	3	.	

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TABLE 8.19: Shift table for Neutrophils

		Lubricat Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	1	2	.	13	4	0.005
		N	:	65	44	2	64	30	
		L	:	6	2	.	5	1	
Baseline vs Day 7-28	Pre-treatment	H	.	2	1	.	10	6	0.026
		N	1	88	16	.	84	8	
		L	1	4	.	1	4	.	
Baseline vs Second Look	Pre-treatment	H	.	3	1	.	9	7	0.090
		N	2	105	6	2	93	2	
		L	3	3	.	2	4	.	

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TABLE 8.20: Shift table for Lymphocytes

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	3	4	.	3	7	.	0.001
		N	51	61	.	27	66	1	
		L	1	1	.	8	8	.	
Baseline vs Day 7-28	Pre-treatment	H	1	3	1	.	8	1	0.013
		N	18	88	1	10	79	2	
		L	.	2	.	6	7	1	
Baseline vs Second Look	Pre-treatment	H	.	5	1	.	4	5	0.032
		N	5	105	4	3	90	3	
		L	.	3	.	5	10	.	

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TABLE 8.21: Shift table for Monocytes

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
			L	N	H	L	N	H	
Baseline vs Day 3	Pre-treatment	H	.	5	6	.	3	7	0.766
		N	1	99	7	1	106	3	
		L	1	2	.	.	1	.	
Baseline vs Day 7-28	Pre-treatment	H	.	7	4	.	2	8	0.137
		N	2	96	3	7	95	1	
		L	1	1	.	.	1	.	
Baseline vs Second Look	Pre-treatment	H	.	2	10	.	3	7	0.912
		N	1	102	5	3	101	5	
		L	1	1	.	.	1	.	

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TABLE 8.22: Shift table for Eosinophils

		Lubricote Gel			Lactated Ringer's Solution			P	
		Post-treatment			Post-treatment				
		L	N	H	L	N	H		
Baseline vs Day 3	Pre-treatment	H	.	3	2	.	3	6	0.206
		N	2	100	9	4	95	3	
		L	1	3	.	1	8	1	
Baseline vs Day 7-28	Pre-treatment	H	.	4	1	.	3	6	0.301
		N	3	94	8	1	86	9	
		L	.	4	.	2	6	1	
Baseline vs Second Look	Pre-treatment	H	.	3	3	.	2	7	0.576
		N	4	106	2	4	94	5	
		L	1	3	.	3	4	1	

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TABLE 8.23: Shift table for Basophils

			Lubricote Gel			Lactated Ringer's Solution			P
			Post-treatment			Post-treatment			P
			L	N	H	L	N	H	
Baseline vs Day 3	Pre-treatment	H	.	7	.	.	5	1	
		N	.	106	2	.	105	2	0.809
		L	4	.	.	7	.	.	
Baseline vs Day 7-28	Pre-treatment	H	.	5	4	.	4	2	
		N	.	96	4	.	93	8	0.590
		L	4	.	.	7	.	.	
Baseline vs Second Look	Pre-treatment	H	.	5	4	.	3	3	
		N	.	102	6	.	103	3	0.676
		L	4	.	.	7	.	.	

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TABLE 9: Abdominal Auscultation and Percussion

Variable	3 Days	Lubricote Gel			Lactated Ringer's Solution			P
		n	N	%	n	N	%	
Bowel Sounds	A	136	/ 143	95.1%	135	/ 138	97.8%	0.336
		133	/ 143	93.0%	132	/ 138	95.7%	0.442
		134	/ 143	93.7%	134	/ 138	97.1%	0.256
		136	/ 143	95.1%	132	/ 138	95.7%	1.000
Fluid Wave	A	1	/ 143	0.7%	0	/ 138	0.0%	1.000
		1	/ 143	0.7%	0	/ 138	0.0%	1.000
		3	/ 143	2.1%	1	/ 138	0.7%	0.623
		3	/ 143	2.1%	0	/ 138	0.0%	0.248
Rebound Pain	A	3	/ 143	2.1%	3	/ 138	2.2%	1.000
		3	/ 143	2.1%	2	/ 138	1.4%	1.000
		15	/ 143	10.5%	9	/ 138	6.5%	0.288
		9	/ 143	6.3%	10	/ 138	7.2%	0.815
7-28 Days	Bowel Sounds	126	/ 130	96.9%	129	/ 134	96.3%	1.000
		126	/ 130	96.9%	130	/ 134	97.0%	1.000
		126	/ 130	96.9%	133	/ 134	99.3%	0.208
		126	/ 130	96.9%	131	/ 134	97.8%	0.719
Fluid Wave	A	0	/ 130	0.0%	0	/ 134	0.0%	0.719
		0	/ 130	0.0%	0	/ 134	0.0%	0.719
		0	/ 130	0.0%	0	/ 134	0.0%	0.719
		0	/ 130	0.0%	0	/ 134	0.0%	0.719
Rebound Pain	A	0	/ 130	0.0%	1	/ 134	0.7%	1.000
		0	/ 130	0.0%	1	/ 134	0.7%	1.000
		6	/ 130	4.6%	2	/ 134	1.5%	0.167
		4	/ 130	3.1%	2	/ 134	1.5%	0.442

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